

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JOHN HANCOCK LIFE INSURANCE
COMPANY, JOHN HANCOCK
VARIABLE LIFE INSURANCE
COMPANY and MANULIFE
INSURANCE COMPANY,

Plaintiffs,

v.

ABBOTT LABORATORIES,

Defendant.

CIVIL ACTION NO. 05-11150-DPW

**ABBOTT'S CORRECTED DEPOSITION COUNTER-DESIGNATIONS FOR
JOHN LEONARD**

Defendant Abbott Laboratories ("Abbott") respectfully submits the attached corrected deposition counter-designations for the November 30, 2007 deposition of John Leonard, M.D., Senior Vice-President of Global Pharmaceutical Research and Development.

Dated: February 22, 2008

Respectfully submitted,

ABBOTT LABORATORIES

By: /s/ Eric J. Lorenzini
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CERTIFICATE OF SERVICE

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on February 22, 2008.

Date: February 22, 2008.

/s/ Ozge Guzelsu

John Leonard Deposition Designations

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
11/30/06	Leonard, John	4:12-5:6					
11/30/06	Leonard, John	8:7-13:15					
11/30/06	Leonard, John	15:3-16:23					
11/30/06	Leonard, John	21:15-25:20					
11/30/06	Leonard, John	26:17-26:23	26:24-27:23				
11/30/06	Leonard, John	28:8-29:13	27:24-28:7				
11/30/06	Leonard, John	30:14-31:19					
11/30/06	Leonard, John	32:12-33:12	33:13-34:9				
11/30/06	Leonard, John	34:11-37:15					
11/30/06	Leonard, John	39:13-39:19					
11/30/06	Leonard, John	41:8-42:24			1	32	
11/30/06	Leonard, John	44:16-45:23			1	32	
11/30/06	Leonard, John	52:7-54:6					
11/30/06	Leonard, John	55:7-56:9					
11/30/06	Leonard, John	56:18-59:4					
11/30/06	Leonard, John	59:19-60:7					

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
11/30/06	Leonard, John	68:3-69:12	69:13-69:18		3	1	
11/30/06	Leonard, John	81:17-86:9			4	M	
11/30/06	Leonard, John	87:5-89:6	89:7-90:18		4	M	
11/30/06	Leonard, John	90:19-92:18			4	M	
11/30/06	Leonard, John	95:22-96:24					
11/30/06	Leonard, John	97:11-102:24					
11/30/06	Leonard, John	103:1-103:20	103:21-104:20		5	Y	
11/30/06	Leonard, John	104:21-107:2	107:3-107:8				
11/30/06	Leonard, John	122:2-124:5	124:6-124:24		7	AE	
11/30/06	Leonard, John	125:1-126:13	126:14-126:20		7	AE	
11/30/06	Leonard, John	133:18-135:12					
11/30/06	Leonard, John	136:7-143:16			10	KY	
11/30/06	Leonard, John	151:11-152:10					
11/30/06	Leonard, John	152:11-155:5			13	CT	
11/30/06	Leonard, John	165:22-167:17			16	IH	
11/30/06	Leonard, John	168:19-169:3			16	IH	
11/30/06	Leonard, John	170:12-170:17	170:18-171:6				
11/30/06	Leonard, John	173:21-175:11	175:12-175:20				

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
11/30/06	Leonard, John	179:4-179:15	179:16-180:1				
11/30/06	Leonard, John	224:10-231:24			27	R	
11/30/06	Leonard, John	234:8-237:11	237:12-237:14		28	EK	
11/30/06	Leonard, John	241:5-241:24			30	MJ	
11/30/06	Leonard, John	254:4-256:7			30	MJ	
11/30/06	Leonard, John	265:12-267:22			35	MR	
11/30/06	Leonard, John	274:13-278:9			38	FY	
11/30/06	Leonard, John	292:8-293:10					
11/30/06	Leonard, John	320:19-322:1					
11/30/06	Leonard, John	324:11-325:2	325:3-325:14				
06/01/07	Leonard, John	338:11-338:15					
06/01/07	Leonard, John	346:17-348:5			45	28	
06/01/07	Leonard, John	348:18-349:9			48	NH	
06/01/07	Leonard, John	351:22-352:10			48	NH	
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06/01/07	Leonard, John	361:3-362:1			49	BH	
06/01/07	Leonard, John	376:24-377:5			50	NE	
06/01/07	Leonard, John	378:1-387:10			50	NE	

Depo Date	Witness	Hancock Designation	Abbott Counter Designation	Abbott Designation	Deposition Exhibit	Plaintiff Exhibit	Defendant Exhibit
06/01/07	Leonard, John	389:4-389:18	389:19-390:14		51	ID	
06/01/07	Leonard, John	390:15-390:20					
06/01/07	Leonard, John	391:4-391:24	392:1-393:23		52	NC	
06/01/07	Leonard, John	394:1-396:3	393:24		52	NC	
06/01/07	Leonard, John	401:3-403:13					
06/01/07	Leonard, John	403:21-414:2			54 55	IO IL	
06/01/07	Leonard, John	432:12-434:18			57	FC	
06/01/07	Leonard, John	436:16-438:12	438:13-438:20				
06/01/07	Leonard, John	439:20-441:9			57	FC	
06/01/07	Leonard, John	444:15-445:10	445:11-445:12				
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06/01/07	Leonard, John	481:16-487:17			64 65	IW FR	
06/01/07	Leonard, John	524:7-524:11					
06/01/07	Leonard, John	526:11-528:10	528:11-529:4		73	PA	

Color Key to Deposition Designations

 **Designation by Plaintiffs**

 **Counter Designation by Defendants**

 **Designation by Defendants**

1 UNITED STATES DISTRICT COURT
2 FOR THE
3 DISTRICT OF MASSACHUSETTS
4 JOHN HANCOCK LIFE INSURANCE)
5 COMPANY, JOHN HANCOCK)
6 VARIABLE LIFE INSURANCE)
7 COMPANY, and MANULIFE)
8 INSURANCE COMPANY (f/k/a)
9 INVESTORS PARTNER INSURANCE) Civil Action No.
10 COMPANY),) 05-11150-DPW
11 Plaintiffs,)
12 -vs-)
13 ABBOTT LABORATORIES,)
14 Defendant.)

15 H I G H L Y C O N F I D E N T I A L

16 The confidential videotaped deposition
17 of JOHN LEONARD, called for examination, taken
18 pursuant to the Federal Rules of Civil Procedure
19 of the United States District Courts pertaining to
20 the taking of depositions, taken before THERESA A.
21 VORKAPIC, a Notary Public within and for the
22 County of Kane, State of Illinois, and a Certified
23 Shorthand Reporter, CSR No. 84-2589, of said
24 state, at Suite 1300, Two North LaSalle Street,

1 Laboratories.

2 MR. WITTE: I'm Pete Witte. I am in-house

3 counsel at Abbott.

4 THE VIDEOGRAPHER: Will the Reporter now

5 swear in the witness, please.

6 (WHEREUPON, the witness was duly

7 sworn.)

8 JOHN LEONARD,

9 called as a witness herein, having been first duly

10 sworn, was examined and testified as follows:

11 EXAMINATION

12 BY MR. DAVIS:

13 Q. Good morning.

14 A. Good morning.

15 Q. Dr. Leonard, would you just state your

16 full name, please, for the record?

17 A. John Martin Leonard.

18 Q. It's correct you are a doctor?

19 A. I'm a medical doctor, right.

20 Q. Doctor, where do you live?

21 A. Here in Chicago.

22 Q. Can you give me the street address,

23 please?

24 A. Sure. 840 North Lake Shore Drive,

1 Apartment 2201, Chicago, Illinois, 60611.

2 Q. Where are you employed?

3 A. Abbott Laboratories.

4 Q. What position do you hold there?

5 A. I am the vice president of Global

6 Pharmaceutical Research & Development.

7 Q. Dr. Leonard, I'm going to ask you a
8 series of questions here today. If at any point
9 in time you don't understand my question, please
10 just let me know and I'll try and give you a
11 clearer question.

12 Do you understand that?

13 A. I understand that.

14 Q. If you respond to my question, I'm
15 going to assume that you understood it; is that
16 fair?

17 A. Yeah, I suppose that's fair. If I need
18 further clarification, I'll bring that up as we
19 go. If I thought I misconstrued it, I'll go back
20 and try and clarify it.

21 Q. Please do. Have you been deposed
22 before?

23 A. I have.

24 Q. On how many occasions?

1 BY MR. DAVIS:

2 Q. That's Norvir?

3 A. That product is called Norvir, yeah.

4 Q. Was that deposition videotaped?

5 A. This is the first time I've been

6 videotaped in a deposition.

7 Q. You said your title is vice president

8 of Global Pharmaceutical Development?

9 A. Global Pharmaceutical Research &

10 Development since April of this year.

11 Q. Who is your current immediate superior

12 at Abbott?

13 A. William Dempsey.

14 Q. How long have you been employed by

15 Abbott?

16 A. Since March of 1992.

17 Q. Would you walk me briefly through the

18 positions that you've held at Abbott since you

19 joined the company?

20 A. If I remember them all, I'll try. I

21 came in March of 1992 and I was the -- what was

22 called at that time the venture head of the

23 anti-viral venture if I remember right. In 1996 I

24 became a divisional vice president for

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1 anti-infective diseases. I think the next year
2 1997, if I remember correctly, I was divisional
3 vice president of ventures and then in 1999, I
4 became corporate vice president for development.
5 Probably in 2001 if I remember, I may be off a
6 year here, I became corporate vice president for
7 global pharmaceutical development. Then in 199 --
8 I'm sorry in 2004, I became corporate vice
9 president of Global Medical & Scientific Affairs
10 until April of this year when I assumed my current
11 position.

12 Q. I'm sorry. The position you took in
13 2004, what position was that, corporate vice
14 president of --

15 A. Global Medical & Scientific Affairs,
16 not technically a part of the research and
17 development organization.

18 Q. Are you currently a part of the
19 research and development organization?

20 A. I head it.

21 Q. Back in 1999 when you were corporate
22 vice president of development, development of
23 what?

24 A. Well, it was called development. It

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1 was in the pharmaceutical group, so even though it
2 was a formal part of the title, I was responsible
3 for the development activities related to some of
4 the pharmaceutical activities at Abbott
5 Laboratories.

6 Q. Some but not all?

7 A. Correct. The company had
8 pharmaceutical development activities that took
9 place in various other operating divisions, some
10 of which were outside the scope of what I did.

11 Q. You are familiar with the Research
12 Funding Agreement between Abbott and John Hancock?

13 A. I know there was an agreement, yes.

14 Q. You are familiar with the particular
15 compounds that became the program compounds
16 encompassed by that agreement?

17 A. I couldn't list them all for you right
18 now without looking at a list, but I know there
19 were several. I'm familiar with most of them,
20 yes.

21 Q. Were those particular -- there were
22 nine of them, let me explain, and we can go
23 through the list if necessary, but is it your
24 recollection that those nine compounds fell within

1 the scope of your responsibilities as corporate VP
2 of development?

3 A. Without confirming with the list, I
4 think certainly most of them. I don't know
5 without looking at it again if all of them were my
6 direct responsibility.

7 Q. How about ABT-594?

8 A. Yes. That was my scope of
9 responsibility.

10 Q. How about ABT-518?

11 A. Yes, it was in my scope of
12 responsibility.

13 Q. And ABT-773?

14 A. Yes, it was in my scope of
15 responsibility.

16 Q. What were your responsibilities as
17 corporate vice president of development?

18 A. Fell into two categories. There was a
19 set of non-clinical activities, and by that I mean
20 things not directly related to the testing of a
21 drug in people, so animal work, statistical work,
22 et cetera, formulation work, and then there was a
23 subset of all of the clinical work that we did
24 that I was responsible for, which included

1 oncology and neuroscience and anti-infective, so
2 773 that you read was an anti-infective product,
3 that clinical team reported into me that was
4 responsible for it, ABT-518, an oncology product,
5 that team reported into me on the clinical side,
6 and ABT-594 was a neuroscience side and it
7 reported into me on the neuroscience side.

8 Q. I think you testified that as best you
9 can recall you took the position of corporate VP
10 of global pharmaceutical development sometime in
11 2001; is that right?

12 A. I think it was 2001, yes.

13 Q. Do you recall approximately when in
14 that year that you took that position?

15 A. I don't recall the precise month. It
16 may have been the spring. I don't remember
17 exactly.

18 Q. Was it before the agreement with John
19 Hancock was executed?

20 A. I don't recall exactly.

21 Q. In your capacity as corporate vice
22 president of development, who was your immediate
23 superior?

24 A. Jeffrey Leiden.

1 Q. What was Dr. Leiden's position at that
2 time?

3 A. At that time I'm not certain because he
4 had several title changes over the course of his
5 time with the company.

6 Q. What's your best recollection of the
7 position that he held?

8 A. He was I think from the time he walked
9 into the company until the day he left chief
10 scientific officer and then he held a variety of
11 other titles related to other pharmaceutical
12 responsibilities.

13 Q. You mentioned that Dr. Leiden left the
14 company. Why did he leave Abbott?

15 A. I don't know. You can ask him.

16 Q. Have you ever discussed that topic with
17 him?

18 A. I haven't talked to him since the day
19 he left.

20 Q. Before he left?

21 A. I was out of the country when it was
22 announced and I didn't speak to him.

23 Q. When you were corporate vice president
24 of development reporting into Dr. Leiden, how

1 A. I don't recall exactly what happened at
2 that time.

3 Q. Doctor, would you give me a brief
4 description of your educational background,
5 please?

6 A. I graduated from high school in 1975 as
7 I recall. I then graduated with a Bachelor of
8 Arts degree from the University of Wisconsin in
9 biochemistry. I attended medical school at Johns
10 Hopkins University. I did a medical internship
11 and residency at Stanford University Hospital.
12 That was from 1983 to 1986. From 1986 to 1989, I
13 was a postgraduate fellow at the National
14 Institutes of Health and the National Institute of
15 Allergy & Infectious Disease.

16 Q. And those positions that you held up
17 until the time that you joined Abbott in March of
18 1992?

19 A. No. I left the NIH in 1989 and I was
20 employed at a company before coming to Abbott.

21 Q. What company was that?

22 A. The company was called G.H. Besselaar
23 Associates.

24 Q. What was their business?

1 A. It was a contract research

2 organization.

3 Q. Does it mean that they conducted

4 clinical trials among other things?

5 A. They did conduct clinical trials among

6 other things.

7 Q. Have you actually conducted clinical

8 trials yourself?

9 A. I have.

10 Q. How many?

11 A. In the context of my employment if

12 that's what you're referring to.

13 Q. Yes.

14 A. Yeah.

15 Q. Have you ever been the subject of a

16 clinical trial?

17 A. I've volunteered. It seems fair,

18 doesn't it?

19 Q. It does seem fair. Tell me how many

20 clinical trials have you personally been involved

21 in supervising or running?

22 A. I don't know that number. It would be

23 substantial number.

24 Q. When is the last time that you actually

1 have not discussed the subject of the deposition,
2 however.

3 Q. Have you talked to any of the people
4 who have been deposed in this matter already
5 regarding their depositions?

6 A. I have not.

7 Q. Have you reviewed any depositions in
8 this matter?

9 A. No.

10 Q. So you haven't seen any deposition
11 transcripts, for example?

12 A. I think I saw some of my own material
13 from the deposition I referred to earlier, but
14 that's the extent of it.

15 Q. Going back to the Research Funding
16 Agreement between John Hancock and Abbott, what
17 involvement did you have in the negotiation of
18 that agreement, if any?

19 A. I did not negotiate the agreement at
20 all.

21 Q. Did you have any contact with anyone at
22 Hancock prior to the execution of the agreement
23 concerning the subject of the agreement?

24 A. The one employee I recollect dealing

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1 with at any point at any time associated with

2 Hancock was Mr. Steve Blewitt.

3 Q. On how many occasions did you

4 communication with Mr. Blewitt about the deal

5 before the deal was done?

6 A. I can't give you a precise number. I

7 remember at least one conversation on the

8 telephone. There may have been two.

9 Q. Did you ever meet Mr. Blewitt in person

10 before the agreement was executed?

11 A. I met him, but I believe it was after

12 it was executed. There was a dinner as I

13 recollect it was to celebrate the signing which I

14 think implied it was already signed, but I don't

15 have clarity with respect to the precise timing.

16 MR. WEINBERGER: Who paid for that dinner?

17 THE WITNESS: I know I didn't.

18 BY MR. DAVIS:

19 Q. You said that you recall at least one

20 conversation with Mr. Blewitt on the telephone; is

21 that right?

22 A. Yes. That's right.

23 Q. Is that a conversation where a Dr. Lynn

24 Klotz also participated?

1 A. That is the conversation I'm referring
2 to, yes.

3 Q. You believe there may have been other
4 communications with Mr. Blewitt, but you don't
5 recall them right now; is that right?

6 A. I know I've talked to him since the
7 deal was signed because there were some
8 conversations that have taken place regarding
9 status of the programs, and what I just don't
10 recollect is it related to some of those questions
11 he and I spoke before the deal was signed, the one
12 I know that I remember is a teleconference with
13 him and I think it was Dr. Klotz.

14 Q. You said you don't remember
15 participating in the negotiation of the agreement.

16 Do you remember reviewing any drafts of
17 the Research Funding Agreement before it was
18 executed?

19 A. What I remember seeing are a series of
20 descriptions of projects. I don't recall looking
21 at financial terms, contracts specifically.

22 Q. As you sit here today, have you ever
23 reviewed the Research Funding Agreement that was
24 executed by John Hancock and Abbott?

1 A. I don't recall reviewing that.

2 Q. When you say you recall descriptions of
3 projects, you mean descriptive memoranda that
4 addressed certain compounds that were encompassed
5 by the agreement?

6 A. I believe that's what they were called
7 if I remember right.

8 Q. When do you recall first reviewing
9 those?

10 A. I'm not going to be able to give you a
11 precise date. There was an extended process that
12 had been gone through where documents were
13 generated and drafts were created. I don't know
14 if I saw all the drafts and I don't know precisely
15 when it began. It was as I recall some months
16 before the deal was ultimately signed.

17 Q. Did you participate in the process of
18 creating those memoranda?

19 A. I didn't write them. I don't remember
20 writing them. I remember being asked to look at
21 them. I don't recall if I looked at all of them.
22 I know I looked at some of them.

23 Q. Did you instruct anyone within Abbott
24 to create those memoranda?

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1 A. I don't remember the circumstances of
2 how they were created. People who worked for me
3 did write the documents. I don't know if they did
4 it on my specific request or if other people -- we
5 are a highly matrixed organization -- asked them
6 to write it. I don't recall that.

7 Q. Was it your understanding at the time
8 that you were reviewing the memoranda that they
9 had been created for the purpose of informing
10 Hancock about the particular compounds that were
11 proposed to be included in the deal?

12 A. Yeah. My understanding is we were to
13 give a general description of the projects and
14 products.

15 Q. Where did you get that understanding?

16 A. You know, I'm not going to be able to
17 pinpoint a conversation for you. There were other
18 people involved who were dealing directly with
19 Hancock in the negotiation. I believe Phil Deemer
20 and maybe Steve Cohen were involved.

21 Q. Who do you recall being the people who
22 negotiated the contract between Hancock and
23 Abbott?

24 A. I'm not sure who was doing it because

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1 we have a business development group and there was
2 corporate people who may have been involved. I
3 try -- my responsibilities are not involved with
4 that at all so I don't know who was speaking to
5 whom, when and where.

6 Q. To your knowledge, you said Mr. Cohen
7 was involved at some level in developing that
8 agreement?

9 A. I remember talking to Mr. Cohen about
10 the documents. In terms of actually creating the
11 agreement if that's what you're asking me, I have
12 no idea what his direct role was.

13 Q. Was Mr. Deemer involved in creating
14 that deal in some way as far as you know?

15 A. I know he was involved. I'm not sure
16 of the precise nature of the involvement.

17 Q. Do you know of anyone else that you
18 recall dealing with within Abbott concerning the
19 terms of that deal or any of the documents
20 associated with that deal?

21 A. The people I was involved with were
22 Steve Cohen and Phil Deemer to the best of my
23 recollection.

24 Q. Did you ever have any discussions with

1 Dr. Leiden regarding the deal with Hancock before
2 it was executed?

3 A. It came up in the course of general
4 conversation.

5 Q. What do you recall? What was the
6 substance of your discussions with Dr. Leiden on
7 that point?

8 A. I don't remember precisely all aspects
9 of what was talked about. Dr. Leiden came to the
10 company some months before the agreement was
11 signed and I'm sure it came up in the context of
12 general planning for -- budgetary planning for the
13 year's activity, the subsequent year, so I'm sure
14 we described it to him in general terms. I'm sure
15 we also described the general purpose of this
16 which was risk sharing and risk mitigation for
17 different development programs.

18 Q. What was your understanding as to the
19 purpose of the deal from Abbott's perspective?

20 A. Risk sharing and risk mitigation. We
21 dealt with what is well known to be a highly risky
22 undertaking, which is drug discovery, in this case
23 drug development.

24 Q. You said it's highly risky. Abbott I

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1 assume is exposed to that risk in some way?

2 A. It's generally known that drug

3 development has no guaranteed outcomes. That by

4 that I mean risky, and we have like every

5 pharmaceutical company programs for which we have

6 no idea what the overall outcome is going to be.

7 I characterize that as high risk.

8 Q. Does Abbott have procedures or policies

9 in place that it uses to try to control the level

10 of risk associated with the particular programs?

11 MR. WEINBERGER: Objection. You may answer.

12 BY THE WITNESS:

13 A. I don't know what control means. We

14 try to mitigate risk, and these are all judgments

15 that are made based on imponderables.

16 BY MR. DAVIS:

17 Q. Does Abbott try to mitigate its risk,

18 in part, for example, by examining success ratios

19 regarding particular compounds or categories of

20 compounds?

21 MR. WEINBERGER: Objection.

22 BY THE WITNESS:

23 A. When we try to understand how a program

24 will unfold, we try to use every bit of

1 information reasonable available to us to make the
2 best judgment for the patients who will be in
3 those trials and for our investors.

4 BY MR. DAVIS:

5 Q. One of the things that Abbott takes
6 into account are success ratios?

7 MR. WEINBERGER: Objection.

8 BY THE WITNESS:

9 A. We consider it. We're not slaves to
10 those numbers. Those are all judgments. In the
11 end it will always come down to judgment,
12 intuition and our best individual assessment for
13 the data before us.

14 BY MR. DAVIS:

15 Q. In some of the information that Abbott
16 considers when it's making its decisions about
17 compounds is up-to-date, current information about
18 the current development status of the compounds?

19 MR. WEINBERGER: Objection.

20 BY THE WITNESS:

21 A. I'm not sure I understand when you say
22 the compounds. Our own compounds or competing
23 compounds? I'm not sure.

24 BY MR. DAVIS:

1 Q. I think we are talking right now about
2 how Abbott goes with mitigating its risk in
3 developing compounds within Abbott. You
4 understand that?

5 A. I think I do. I'm not precisely sure
6 what's going on in your mind right now because it
7 may mean something -- let me tell you --

8 MR. WEINBERGER: Let's make sure you're
9 answering the same question he's asking.

10 BY THE WITNESS:

11 A. Maybe you could help me out a little
12 bit.

13 BY MR. DAVIS:

14 Q. A moment ago we were discussing I
15 understood how Abbott goes about mitigating its
16 risk in the development of pharmaceutical
17 compounds.

18 Do I have that correct?

19 A. That is correct.

20 Q. I want to question you further in that
21 area.

22 A. Sure.

23 Q. One of the things you said that Abbott
24 considers among all of the information that it

1 takes into account in attempting to mitigate its
2 risk are success ratios, correct?

3 A. We take it into consideration. It does
4 not -- we are not slaves to that information.
5 It's a general guide that may tell us what has
6 happened generally speaking for those who have
7 gone before us.

8 Q. Is it another item of information that
9 Abbott takes into account in attempting to
10 mitigate its risk information about the current
11 development status of the particular compound
12 that's being considered?

13 MR. WEINBERGER: Its own compound?

14 MR. DAVIS: Yes.

15 BY THE WITNESS:

16 A. Yeah, I mean, if you're asking me do we
17 think about our drug and what we already know
18 about it before we do the next step, of course, we
19 do.

20 BY MR. DAVIS:

21 Q. So, for example, are you involved
22 sometimes in making decisions about whether Abbott
23 will continue to pursue development of a
24 particular compound?

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1 A. Sometimes I am, sometimes I'm not.

2 Q. In take making those decisions, do you

3 want to know?

4 MR. DAVIS: Let's take a break here for a

5 second and go off the record.

6 THE VIDEOGRAPHER: Going off the video record

7 at 9:42 a.m.

8 (WHEREUPON, a recess was had.)

9 THE VIDEOGRAPHER: We're going back on the

10 video record at 9:45 a.m.

11 BY MR. DAVIS:

12 Q. Dr. Leonard, I'm sorry for the

13 interruption.

14 Before we broke, we were talking about

15 sort of decision making within Abbott about

16 pharmaceutical compounds and the development of

17 pharmaceutical compounds and I think you testified

18 that you have sometimes been involved in that

19 process; is that right?

20 A. Sometimes, yes.

21 Q. On those occasions that you've been

22 involved, have you wanted to know, for example, in

23 making your decisions or your recommendations of

24 the current status of any clinical trials

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1 involving those particular compounds?

2 A. I like to know what's necessary to make

3 an informed decision.

4 Q. Does that include the current status of

5 any clinical trials involving the compounds in

6 question?

7 A. In a very general sense, yes.

8 Q. You would want the most up-to-date

9 information, correct?

10 A. I would want the most up-to-date

11 information that is important for making a

12 decision.

13 Q. Which would include to the best of your

14 ability the most up-to-date information regarding

15 clinical trials that you could obtain within

16 Abbott, correct?

17 MR. WEINBERGER: I think that's been asked

18 and answered three times now.

19 BY MR. DAVIS:

20 Q. Did you respond?

21 A. I've already answered the question.

22 Q. So your answer to my question is you've

23 answered it?

24 A. Could you repeat the question? Now I'm

1 confused with what you've asked me.

2 MR. DAVIS: Could you repeat the question,

3 please.

4 (WHEREUPON, the record was

5 read by the reporter.)

6 BY THE WITNESS:

7 A. Some information is more important than

8 others and it all doesn't have to be absolutely

9 current to make an informed decision.

10 BY MR. DAVIS:

11 Q. You would agree with me, however, that

12 the status of clinical trials involving a compound

13 that you're considering whether to further develop

14 would be important information?

15 MR. WEINBERGER: Objection. This has been

16 asked and answered now four times.

17 MR. DAVIS: I don't think so.

18 MR. WEINBERGER: I do.

19 BY THE WITNESS:

20 A. I don't even know what status means in

21 your question. I'm very confused by that.

22 BY MR. DAVIS:

23 Q. You don't know what the phrase "status

24 of clinical trials" means?

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1 A. No. I don't know what it means to you.

2 Q. Well, does it have any meaning to you,

3 Doctor?

4 A. Not right now.

5 Q. Do you periodically in the course of

6 your work at Abbott receive updates regarding

7 clinical trials that are ongoing involving drugs

8 under development?

9 A. I receive general updates which are the

10 judgments of people in the organization running

11 those trials.

12 Q. How do you receive those updates

13 usually?

14 A. Currently?

15 Q. Yes.

16 A. I receive them directly from somebody

17 sending me a note, calling me if they think

18 there's something particularly urgent or currently

19 in the last few months we have a monthly review

20 where individuals are given the opportunity to

21 describe verbally to me in a meeting what they

22 think is important in a program.

23 Q. Back in the 2000, 2001 time frame, did

24 you receive periodic updates regarding clinical

1 trials involving compounds that fell within your

2 area of responsibility?

3 A. I will not be able to know the precise

4 chronology. There was a time when different types

5 of documents, reports were created, some of those

6 were called monthly project status reports that

7 was done for awhile, started and stopped. It was

8 not uniformly used and then there was a time where

9 highlights would be generated and that was not

10 routinely continued because it was viewed to be

11 not particularly useful at the time.

12 Q. But you recall some time perhaps around

13 that time frame receiving some sort of periodic

14 highlights regarding clinical trials?

15 A. I guess what I'm saying is that I knew

16 documents were provided. I just don't know the

17 precise time frame in the chronology that I think

18 you're asking me about.

19 Q. What ways do you recall receiving

20 updates of clinical trials since, say, the 1999

21 period to the present?

22 MR. WEINBERGER: I object to the form of the

23 question. Go ahead.

24 BY THE WITNESS:

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1 A. I think I just lost my microphone. I'm

2 sorry. It got caught on something.

3 There was a time when project teams

4 would create something called a monthly project

5 status report. This was done inconsistently. I

6 remember we had different development teams

7 reporting in different parts of the organization

8 and I would have one centralized way of doing this

9 and then there was a time when brief description,

10 sometimes as short as a sentence, were used to

11 describe a program on a monthly basis.

12 BY MR. DAVIS:

13 Q. Were the brief descriptions called the

14 highlights?

15 A. That's what I'm referring to, yes.

16 Q. Who was responsible for preparing the

17 monthly project status reports that you referred

18 to?

19 A. I can't tell you the precise person

20 because each team of those different development

21 teams would have responsibility of entering

22 information and then making it available.

23 Q. Someone on the project development

24 team?

1 others, assembled it and forwarded it on.

2 Q. When you say you collated it, you would
3 take information supplied to you and put it into a
4 format to pass it on to your superiors; is that
5 right?

6 A. Yeah. I mean, that's correct, what I
7 mean is somebody would forward to me some
8 sentences and I would take those sentences,
9 collect them with sentences that came from other
10 teams and make a list of all of these different
11 projects, put them in one form and then forward
12 them on.

13 Q. In the 2000, 2001 time frame, did you
14 attempt to try to keep yourself reasonably well
15 informed regarding the status of the development
16 of the various compounds that fell within your
17 area of responsibility?

18 A. I tried to keep myself reasonably
19 informed, yes.

20 Q. Going back to discussions you had with
21 Dr. Leiden for a moment I think about this
22 agreement with Hancock, you said you didn't recall
23 precisely what discussions you may have had.

24 As you sit here today, do you recall

1 A. I don't remember anything specifically.

2 Q. Is it fair to say, Dr. Leonard, that
3 you've now told me everything that you can recall
4 regarding your discussions with Dr. Leiden on the
5 John Hancock Research Funding Agreement?

6 A. I'm telling you everything I can recall
7 right now.

8 MR. DAVIS: Let's mark this as the first
9 exhibit, please.

10 (WHEREUPON, a certain document
11 was marked Leonard Deposition
12 Exhibit No. 1, for identification,
13 as of 11/30/06.)
14 (WHEREUPON, the document was
15 tendered to the witness.)

16 BY MR. DAVIS:

17 Q. Dr. Leonard, you have what has been
18 marked as Exhibit 1 in your deposition.

19 Let me ask you, have you seen this
20 document before, sir?

21 A. Not in its completely printed form.

22 Q. You've seen portions of it before?

23 A. I am assuming that the descriptive
24 memoranda appended at the end of the document are

1 documents I've seen previously.

2 Q. The descriptive memorandum that we

3 referred to earlier today; is that right?

4 A. I'm assuming these are the same ones.

5 Q. Did you review descriptive memos for

6 all of the program compounds before the deal with

7 John Hancock was executed?

8 A. I don't remember. I saw a variety of

9 documents in various stages of development. If I

10 saw every single one in its final form, I don't

11 remember that.

12 Q. Do you recall whether there was someone

13 else within Abbott that also was responsible for

14 reviewing descriptive memos?

15 A. Project team leaders, when they

16 generated the documents, they may have seen them

17 after I did. They may have modified them after I

18 did.

19 Q. Do you recall that it was one of your

20 responsibilities with respect to this deal to

21 review the descriptive memos for accuracy?

22 A. I may have been asked to do that by

23 individuals. I don't recall that it was a

24 specific responsibility that I had.

1 long time ago, I don't remember all of the
2 circumstances related to this. I see literally
3 hundreds of documents during the course of a month
4 and you can multiply that by the last five, six
5 years.

6 What I remember is that documents came
7 to me usually individually tied to circumstances
8 that I don't know about. I don't know why a
9 document was ready at any one point in time and I
10 don't know why I was asked to look at that
11 particular document.

12 BY MR. DAVIS:

13 Q. You see this document the agreement
14 itself is dated as of March 13, 2001.

15 A. I see that.

16 Q. Do you recall reviewing descriptive
17 memos regarding the program compounds that are
18 encompassed by this agreement shortly before this
19 deal was executed?

20 A. I don't know if I looked at every
21 single document shortly before this agreement was
22 signed.

23 Q. Did you look at some of them?

24 A. I may well have.

1 Q. As you sit here today, do you recall

2 doing that?

3 A. I recall being asked to look at some

4 documents before the agreement was signed.

5 Q. Did you look at a descriptive memo

6 concerning ABT-518 shortly before the agreement

7 was signed?

8 A. I don't recall specifically.

9 Q. Did you look at a descriptive memo

10 regarding ABT-594 shortly before the agreement was

11 signed?

12 A. I don't recall if I looked specifically

13 at that document shortly before it was signed.

14 Q. How about a descriptive memo for

15 ABT-773 shortly before the agreement was signed?

16 A. I don't recall if I looked specifically

17 at that document shortly before the agreement was

18 signed.

19 Q. Do you believe that you reviewed

20 descriptive memos with respect to those three

21 compounds at some point in time before the

22 agreement was signed?

23 A. I believe I did, yes.

24 Q. Dr. Leonard, would you turn to the

1 that's Bates numbered 8104 for a moment?

2 A. Warranties and Indemnity?

3 Q. Correct. Near the bottom of that page

4 you see there is a Section 12.2 entitled Abbott's

5 representations and warranties; do you see that?

6 A. I see it.

7 Q. Do you recall ever reviewing any

8 representations or warranties that Abbott made to

9 John Hancock in the context of this deal?

10 A. I don't know what those words mean. I

11 reviewed descriptive memoranda if that's what

12 you're -- if those are the documents.

13 MR. WEINBERGER: I don't think that's what

14 he's asking.

15 THE WITNESS: No?

16 BY MR. DAVIS:

17 Q. Again, I'll represent to you,

18 Dr. Leonard, in this document under this Section

19 12.2 there are a series of representations and

20 warranties that Abbott made to Hancock.

21 I guess my question is do you recall --

22 take a moment, please, and look at those and see

23 if you recall ever reviewing any of those before

24 the deal was signed? And actually let me speed it

1 up a little bit. I'll direct you first, please,
2 if you look at the next page, 8105, do you see
3 there is a Subsection D?

4 A. I see D.

5 Q. Would you read that to yourself and
6 tell me if you recall ever reading that before?

7 A. I don't recall reading that.

8 Q. Would you turn to two more pages to
9 8107 and look at the Subsection I and please read
10 that to yourself and tell me if you ever recall
11 reading that before?

12 A. I don't recall reading that previously.

13 Q. Would you turn to the next page,
14 please, Page 8108, and read Subsection M to
15 yourself and tell me, please, if you recall ever
16 reading that before?

17 A. I don't recall reading that previously,
18 no.

19 Q. When you were reviewing the descriptive
20 memoranda of program compounds before this deal
21 was executed, did you understand that you were
22 doing so in order to confirm the accuracy of the
23 information contained therein?

24 A. As I understood it at that time, yeah.

1 Q. Were you doing it to determine whether
2 all of the material information concerning those
3 compounds was contained in the descriptive memos?

4 A. Material in the sense of what was
5 necessary to understand what was going on the in
6 the project, yes.

7 Q. So, for example, if you would look
8 again at Page 8107, you see there is a reference
9 there on Subsection I to Compound Reports, do you
10 see that?

11 A. I see it underlined there, yes.

12 Q. If you take a look at Exhibit 12.2 to
13 this agreement, 12.2 I, and those begin on page --
14 it's the Bates No. 8152.

15 A. 8152. Okay.

16 Q. Do you see that?

17 A. Yep.

18 Q. If you just look behind that page,
19 you'll see the descriptive memoranda that we've
20 been discussing, correct?

21 A. ABT-773.

22 Q. You see that and there are others
23 besides the 773 one, you can confirm that for
24 yourself, but you see that there is a series of

1 descriptive memoranda here?

2 A. Yes.

3 Q. And you understand that the descriptive
4 memoranda are the compound reports that are
5 referred to in Subsection I?

6 A. Okay, I do.

7 Q. When you were reviewing the compound
8 reports, were you reviewing them to determine
9 whether they contained any untrue statement of
10 material fact?

11 MR. WEINBERGER: He's answered that question.

12 BY THE WITNESS:

13 A. I was asked to look at these for
14 general accuracy, which I did.

15 BY MR. DAVIS:

16 Q. My question is slightly different. I'm
17 reading from the section of Subsection I on
18 Page 8107 and asking you whether when you reviewed
19 the descriptive memoranda when you were reviewing
20 them to determine whether they contained any
21 untrue statement of material fact?

22 MR. WEINBERGER: Are you asking whether
23 someone used those specific words in asking him to
24 review that material? Is that what you're asking?

1 MR. DAVIS: I'm asking him whether that
2 accurately describes what he understood he was
3 doing.

4 BY THE WITNESS:

5 A. I was unaware of this statement. I did
6 not read this statement before I have read it. I
7 was asked to make a general review as to the
8 general accuracy of the program, which is what I
9 did.

10 BY MR. DAVIS:

11 Q. When you reviewed the descriptive
12 memos, did you review them to determine whether
13 they omitted to state any material fact?

14 A. No, not that I recall. I was asked to
15 make general assessments as to the accuracy of the
16 program which was described, and that's what I
17 did.

18 Q. Did you do any due diligence yourself
19 regarding the status of the particular program
20 compounds in order to convince yourself of the
21 accuracy or completeness of the descriptive memos?

22 MR. WEINBERGER: Objection.

23 BY THE WITNESS:

24 A. I spoke generally with the project

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1 teams and asked them to write -- they had been
2 asked -- in some cases I may have asked them, in
3 other cases, they may have been asked by the other
4 individuals I mentioned, to draft up the
5 documents. I did not give them the structure or
6 the format or the template. They were asked to
7 complete it and to do so to the best of their
8 ability, opportunity, overview, marketplace, et
9 cetera. I mean, there's a variety of different
10 things that they were asked to complete. I did
11 not go and independently audit every single fact
12 that was contained in the documents.

13 BY MR. DAVIS:

14 Q. I just want to make sure that I fully
15 understand what you did.

16 You understood that the descriptive
17 memoranda had been assembled by people working on
18 the various project teams for the compounds that
19 were described in the memoranda; is that correct?

20 A. That's correct.

21 Q. Did you -- so you took it that they
22 would give you complete and accurate information;
23 is that fair to say?

24 A. I don't know what complete means. I

1 assume that they would give relevant information
2 to complete the sections of the template as laid
3 out.

4 Q. Did you do anything else to determine
5 whether the information that had been provided to
6 you by the project teams was accurate?

7 A. If I knew something was inaccurate
8 based on my review of -- based on reports or any
9 other information I was aware of, I would respond
10 to that and correct it.

11 Q. So other than anything that stood out
12 as inaccurate based on your own knowledge, you
13 wouldn't have spotted it; is that correct?

14 A. Well, I don't know how I could know it.
15 The people closest to the projects are the ones
16 who have all of the information. I get the
17 information from them.

18 Q. Did you go back and look at any files
19 or look at any updated reports, either monthly
20 status reports or highlights, with respect to the
21 particular compounds and compare them against the
22 descriptive memoranda?

23 A. I don't recall precisely what I did. I
24 would point out that those project reports are

1 written by the project teams themselves.

2 Q. You don't recall doing that?

3 A. I don't specifically -- I may have. I

4 don't recall specifically what I did.

5 Q. What I'm entitled to, I think, Doctor,
6 is your best memory, so I'm not asking you to
7 speculate. I'm asking you if you recall doing so.

8 MR. WEINBERGER: He just answered that. He
9 gave you his testimony. He said, "I don't recall
10 whether I did or not." I don't know what else you
11 want.

12 BY MR. DAVIS:

13 Q. You said you may have but you don't
14 recall doing that; is that right?

15 MR. WEINBERGER: That's what he said.

16 BY THE WITNESS:

17 A. I don't recall.

18 BY MR. DAVIS:

19 Q. Do you recall doing anything else to
20 determine the accuracy or the completeness of the
21 descriptive memoranda?

22 A. I don't recall.

23 Q. Did you ask anyone else within Abbott
24 to assist you in the task of reviewing the

1 descriptive memorandum?

2 A. If by that question you mean did I ask
3 the teams to assemble the documents, yes, and I
4 asked that individuals in those areas who were
5 directly responsible to review the documents for
6 accuracy. They are the ones who know the
7 information. I get the information from them.

8 Q. So, for example, the descriptive memo
9 for ABT-594, who did you ask to review that
10 document for accuracy and completeness as best you
11 recall?

12 A. I'm not going to recall specifically
13 because I just can't. I already said I can't
14 remember if Dr. VerLinden was responsible at that
15 time in that area or if it was limited to
16 Dr. McCarthy who I believe was assembling this
17 information at that time.

18 Q. The same would be true with respect to
19 ABT-518; you don't recall specifically who you
20 asked to review it?

21 A. Well, Doctor -- I do remember Dr. Nisen
22 was responsible for that area. I'm assuming that
23 he was the last person to review that for accuracy
24 before it came to me.

1 think we try to do all our work as efficiently as
2 we know how to do it.

3 MR. DAVIS: Let's mark this as the next
4 Exhibit, Exhibit 3.

5 (WHEREUPON, a certain document
6 was marked Leonard Deposition
7 Exhibit No. 3, for identification,
8 as of 11/30/06.)

9 (WHEREUPON, the document was
10 tendered to the witness.)

11 BY MR. DAVIS:

12 Q. Dr. Leonard, you said I think earlier
13 today that you recalled that you thought you had
14 reviewed different versions of descriptive memos
15 at different points in time; is that right?

16 A. I did say that, yes.

17 Q. Do you recall whether drafts of the
18 descriptive memoranda were sent to you or funneled
19 to you in some way for your review?

20 A. What I recall, and this may be
21 incomplete, is that oftentimes they would come to
22 me one by one as they were assembled. And
23 typically they would be delivered to me by Steve
24 Cohen. He would say could you take a look at this

1 for me and I would do that.

2 Q. When you received the drafts, what did

3 you do with them?

4 A. I don't recall specifically. I'm sure

5 if he asked me to take a look at them, I took a

6 look at them.

7 Q. When you looked at them, what were you

8 looking for?

9 A. I don't recall his specific

10 instructions at that time, but I probably was

11 asked to look for general accuracy, which I

12 probably did.

13 Q. Do you recall at any point in time

14 making or directing someone to make changes in any

15 of the drafts of the descriptive memos?

16 A. I believe I asked for some changes. I

17 don't recall if I made them myself or if others

18 did them for me.

19 Q. What changes do you recall either

20 making or asking someone to make?

21 A. I don't recall precisely. There were

22 many documents I looked at.

23 Q. Do you recall what compounds the

24 changes pertained to?

1 Q. So the answer to my question is yes?

2 A. Was there doubt about whether or not

3 this would be successful? Absolutely.

4 MR. DAVIS: Would you go and please reread my

5 question?

6 MR. WEINBERGER: I think the answer to your

7 question was what he answered.

8 (WHEREUPON, the record was

9 read by the reporter.)

10 BY THE WITNESS:

11 A. We thought it was most likely that the

12 product would not succeed.

13 BY MR. DAVIS:

14 Q. You had heard that before the ASCO

15 conference?

16 A. Well before the ASCO conference.

17 Q. To your knowledge, are you aware that

18 Abbott halted the Phase I clinical trial of

19 ABT-518 for a period of time in March of 2001?

20 A. Yes. I believe there was a -- I don't

21 recall precisely, if there was 24 hours, 48 hours,

22 a very, very brief halt, yes.

23 Q. When you say it's only 24, 48 hours,

24 how long actually was the clinical trial halted?

1 How long was enrollment actually stopped in the
2 trial?

3 A. I don't remember precisely. My general
4 recollection is that it was very, very brief.

5 Q. Do you know how long it took after the
6 trial had been halted to restart the trial?

7 A. I don't know that, no. Well, restart,
8 I don't understand what you mean by that term,
9 enroll the next patient or to -- I don't know what
10 you're asking me.

11 Q. How long after the trial was halted did
12 it take to actually enroll the next patient?

13 A. That I don't know.

14 Q. Were you involved in the decision at
15 Abbott to halt that trial in March of 2001?

16 A. I was aware of it. It wasn't my
17 decision and I wanted to continue the program.

18 Q. How did you first become aware of that
19 decision?

20 A. I generally recollect a series of
21 meetings where we were reviewing programs in
22 general. We were looking at our portfolio in
23 general at the company at the time, and I recall
24 in this meeting, Dr. Leiden, my boss, the chief

1 scientific officer, was concerned about the low
2 prospects of success for this particular compound.

3 Q. To your knowledge, is it Dr. Leiden who
4 made the decision to halt that clinical trial in
5 March of 2001?

6 A. He did.

7 Q. Were you present at the time that
8 Dr. Leiden issued the instruction to halt the
9 trial?

10 A. I was.

11 Q. Precisely when did that occur?

12 A. I don't remember. I'm going to guess
13 the March time frame, March, April. I need to be
14 reminded.

15 Q. I'm sorry. I'm not supposed to
16 interrupt.

17 You recall it occurred at a meeting?

18 A. Yes.

19 Q. Who else was present at the meeting?

20 A. You know, I'm not going to be able to
21 remember precisely. We had a whole series of
22 meetings that were taking place apprising
23 Dr. Leiden of our portfolio in its totality, so I
24 would expect that a large number of people were

1 present at that meeting.

2 MR. DAVIS: Let's mark this as the next

3 exhibit, please.

4 (WHEREUPON, a certain document

5 was marked Leonard Deposition

6 Exhibit No. 4, for identification,

7 as of 11/30/06.)

8 (WHEREUPON, the document was

9 tendered to the witness.)

10 BY MR. DAVIS:

11 Q. Dr. Leonard, you have what's been

12 marked as Exhibit 4 which appears to be a set of

13 presentation slides dating from March 7th to the

14 9th, 2001.

15 A. I have it.

16 Q. Concerning ABT-518?

17 A. I have it.

18 Q. Have you seen these slides before?

19 A. They look familiar to me, yes.

20 Q. You recall that in the week that

21 included March 7th, March 9th, there was a series

22 of meetings with Dr. Leiden and others within

23 Abbott to do a review of Abbott's drug development

24 portfolio?

1 A. That's the meeting I'm referring to.

2 Q. Do you believe that the meeting with
3 Dr. Leiden in which he issued the order to halt
4 the Phase I clinical trial of ABT-518 was issued
5 in that time frame?

6 A. I think it was as a result of this. I
7 don't recall specifically, but I believe that's
8 the case.

9 Q. Was the order issued while the meeting
10 was still under way or was it after the meeting
11 had ended?

12 A. You know, I can't remember
13 specifically. I know that as part of this we
14 would have executive sessions where a subset of
15 the group would talk about this, and I don't
16 remember if it was in a general meeting or in a
17 subsequent session. I don't recall.

18 Q. As best you recall, precisely what did
19 Dr. Leiden instruct people to do at that point in
20 time with respect to 518?

21 A. He wanted us to put the program on hold
22 or stop it as I recall. We, those of us who are
23 more familiar with the compound than he was
24 because I think he was learning about it for the

1 first time there, tried to remind him of the
2 competitive advantages that we believed we had and
3 because we had a variety of other things to attend
4 to in that session, he told us to put it on hold
5 and we moved on.

6 Q. So when Dr. Leiden said put it on hold,
7 you and others at Abbott did as instructed; is
8 that correct?

9 A. We complied with the mandate, yes.

10 Q. Who below Dr. Leiden went out and
11 instructed the people who work on that clinical
12 trial to actually halt the trial?

13 A. As I recall, Dr. Nisen may have been
14 there so I don't know if I told Perry or Perry
15 heard it first hand, but he would have been the
16 person to either do it himself or have people on
17 his team carry out that instruction.

18 Q. What did you understand to be the
19 affect of halting the trial? What did you
20 understand would happen as a result?

21 MR. WEINBERGER: Objection.

22 BY THE WITNESS:

23 A. I don't recall specifically. What I
24 don't recall is if in Dr. Leiden's mind the

1 program was not to proceed or if we were going to
2 come back and review it in the context of
3 additional information.

4 BY MR. DAVIS:

5 Q. You said that, again, you were present
6 at the time that Dr. Leiden made this decision as
7 best you recall?

8 A. As best I recall, yes.

9 Q. What was it that -- did Dr. Leiden
10 explain his decision at that time?

11 A. No. We were going very quickly through
12 programs. I don't recall the specific discussion
13 at the time.

14 Q. Did Dr. Leiden express any concerns
15 about the prospects for 518 at that meeting?

16 A. Again, I have no specific recollection.
17 I remember generally his believing that this was a
18 particularly high risk program and he was
19 concerned about that.

20 Q. Do you recall any discussion about what
21 had happened or any information that had come out
22 regarding any competitor compounds?

23 A. I believe that there was a modicum of
24 clinical information available at that time and

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1 what I remember was that there was titillating
2 data that had come from one competitor which was I
3 think British Biotech as I recall that was not
4 definitive by any stretch of the imagination, but
5 it was one of the earlier compounds and I think
6 some people were more optimistic than Dr. Leiden
7 was about what that data meant for the field in
8 general.

9 Q. Do you recall at that meeting
10 discussing that the development of Marimastat had
11 been discontinued by British Biotech prior to the
12 meeting?

13 A. I remember British Biotech
14 discontinuing their program or that compound. I
15 don't recall when. If I could add one thing, one
16 of the issues with the field in general was
17 toxicity and separating out efficacy from toxicity
18 was the major goal, which going back to our
19 question earlier, we believed we had very
20 substantial prospects for doing based on our
21 preclinical animal work. British Biotech failed
22 to do that.

23 Q. If you take a look at the page that's
24 numbered ending in 3230?

1 A. I've got it.

2 Q. You see that there are a couple of
3 slides on that page. One on the bottom is
4 entitled Potential issues/Threats/Negatives; do
5 you see that?

6 A. I do.

7 Q. Which of the issues, threats or
8 negatives that you see listed there were ones that
9 you believed caused Dr. Leiden to issue the halt
10 order in March of 2001?

11 MR. WEINBERGER: Objection. That calls for
12 speculation.

13 BY MR. DAVIS:

14 Q. To the best of your recollection of
15 what was discussed, Dr. Leonard.

16 A. These are potential issues, threats,
17 negatives for ABT-518. If I could read this,
18 there's toxicity that occurs in animals, efficacy
19 says data released from competitors may cast doubt
20 on the class, which means it was far from
21 definitive that the compound would be successful,
22 clinical recruitment problems, extensive protocol
23 prohibited medications, I can't read that last
24 word. I'm not sure I understand what that means.

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1 MR. WEINBERGER: You know, I think he's
2 asking you if based on this you can tell him what
3 concerns Leiden expressed, not just to interpret
4 the document, is that right, Brian?

5 MR. DAVIS: What I'm asking him to do -- yes.

6 BY MR. DAVIS:

7 Q. I don't want you to interpret the
8 document, Doctor. Again, I'm asking you to
9 identify if you can on this slide which of the
10 issues, threats or negatives were ones that you
11 understood at the time were driving or helping to
12 drive Dr. Leiden to his decision to order a halt
13 of the Phase I clinical trial of 518?

14 A. I don't know specifically. I'm sure
15 it's a gestalt of overall risk, early program in
16 general accompanied by this panoply of
17 considerations may have caused him to think what
18 he did.

19 Q. There's a reference here under
20 Efficacy, "Data released from competitors may cast
21 doubt on class."

22 What data regarding efficacy from
23 competitors did Abbott have as of March 7th to
24 9th, 2001 that's referenced here?

1 A. I don't know specifically. I know
2 there was some information generally available
3 that British Biotech had released. There's
4 another company that had some information that had
5 been publicly disclosed.

6 Q. Is it fair to say that you understood
7 that Dr. Leiden was ordering a halt of the Phase I
8 clinical trials of ABT-518 because he was -- had
9 become pessimistic about the prospects for that
10 compound?

11 MR. WEINBERGER: Objection.

12 BY THE WITNESS:

13 A. I don't know what that means when
14 there's a 95 percent chance that anything is going
15 to fail when you begin it at this stage.

16 BY MR. DAVIS:

17 Q. Did you understand at the time that
18 Dr. Leiden ordered a halt to that clinical trial
19 that Dr. Leiden was making a decision that Abbott
20 shouldn't invest any further beyond what was
21 necessary to develop that compound?

22 MR. WEINBERGER: Objection. I just want it
23 to be clear you're entitled to get from him what
24 Leiden said to him, but you're not entitled to ask

1 him to speculate what was in Dr. Leiden's head.

2 MR. DAVIS: I'm not asking him to speculate.

3 I'm asking Dr. Leonard for his understanding what
4 was occurring at the time. He said he was present
5 so I'm asking Dr. Leonard for your understanding.

6 BY MR. DAVIS:

7 Q. Was it your understanding at the time
8 that what Dr. Leonard was doing -- I'm sorry.

9 Was it your understanding, Dr. Leonard,
10 that what Dr. Leiden was doing at the time that he
11 halted that trial was to make a decision that
12 Abbott should not invest any further in ABT-518?

13 A. I don't recall specifically. I know we
14 halted the program and I can't remember if it was
15 with the intention to come back and review it
16 further or not, and I think Dr. Leiden believed
17 the program was high risk as we all did and wanted
18 to make a decision based on that.

19 Q. Did you understand that what Dr. Leiden
20 wanted to do in part was to cease Abbott's
21 investments in 518?

22 MR. WEINBERGER: I think he just answered
23 that. I think he answered it three times.

24 MR. DAVIS: I disagree.

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1 programs as they understood at that point in time.

2 Q. You understood at that point in time

3 that Dr. Leiden was saying halt the Phase I

4 clinical trial of ABT-518 because I don't think,

5 "I" being Dr. Leiden, don't think that it makes

6 sense for Abbott to continue to put money into the

7 development of this compound; do you agree with

8 that?

9 MR. WEINBERGER: If you want to know what

10 Leiden said, ask him. You're putting words into

11 his mouth.

12 MR. DAVIS: Please, you can state your

13 objections. Please don't interrupt my

14 questioning.

15 BY THE WITNESS:

16 A. I don't recall what he said.

17 BY MR. DAVIS:

18 Q. Is that your understanding of what he

19 was --

20 A. I don't recall.

21 Q. Was the halt on the -- strike that.

22 Whom do you recall discussing

23 Dr. Leiden's instruction that Abbott halt the

24 Phase I clinical trial of ABT-518 with within

1 Abbott?

2 A. I recall generally talking with

3 Dr. Nisen.

4 Q. Anyone else?

5 A. No, not that I recall specifically.

6 Q. Do you recall any discussions on that

7 topic with Phil Deemer?

8 A. I may have. I don't specifically

9 recall those discussions.

10 Q. Do you recall generally any discussions

11 with Mr. Deemer on that topic in March of 2001?

12 A. I don't know if we spoke. I don't

13 specifically recall that.

14 Q. Do you recall that at some point in

15 time after Dr. Leiden instructed that that Phase I

16 trial be halted that the trial was resumed?

17 A. It was resumed subsequently. I

18 remember that.

19 Q. Right now you don't know precisely when

20 it was resumed; is that right?

21 A. Not without -- I don't know

22 specifically. What I recall was it was resumed

23 very, very shortly thereafter.

24 Q. Why was it resumed?

1 A. I'm doing it again. I'm sorry. I
2 remember going back and talking to Dr. Leiden --
3 there is tape on your wire that became taped to my
4 shoe. I'm sorry here.

5 Could you repeat the question? I'm
6 sorry.

7 MR. DAVIS: Would you just reread the
8 question?

9 (WHEREUPON, the record was
10 read by the reporter.)

11 BY THE WITNESS:

12 A. Why was the trial resumed?

13 Q. Yes.

14 A. I remember generally discussing with
15 Dr. Leiden why we believed that our compound had
16 prospects that were different from other compounds
17 in the field. We had a preclinical hypothesis
18 that had not yet been ruled out by any clinical
19 data and therefore any information that was out
20 there at that time probably did not bear directly
21 on the molecule.

22 Secondly, I reminded him that we had a
23 partner in this program and this was part of our
24 general risk mitigation strategy of risk sharing

1 and that we should proceed.

2 Q. When you say you had a partner in the
3 program, you're referring to John Hancock?

4 A. I am.

5 Q. You are?

6 A. I am.

7 Q. And so is it fair to say that the
8 decision to restart the Phase I clinical trial
9 within Abbott was turned in part on the fact that
10 Abbott was entering into the Research Funding
11 Agreement with John Hancock?

12 MR. WEINBERGER: Objection.

13 BY THE WITNESS:

14 A. I don't think that's true at all.

15 BY MR. DAVIS:

16 Q. Then how was it that the fact that
17 Abbott had a partner for ABT-518 in John Hancock
18 that caused you to go to Dr. Leiden and say please
19 restart this clinical trial?

20 A. The program, my recommendation to
21 proceed on this program was based entirely on the
22 prospects, the medical prospects, preclinical
23 prospects of the program. My recommendation was
24 that we should proceed because I thought that the

1 hypothesis still stood and bore testing.

2 Q. How was it relevant to your discussion

3 with Dr. Leiden about why Abbott should restart

4 the Phase I clinical trial for ABT-518 that Abbott

5 was entering into the Research Funding Agreement

6 with John Hancock?

7 A. I don't know how it bears on the

8 Research Funding Agreement at that point in time.

9 Generally speaking I reminded him that we had a

10 risk mitigation, risk sharing approach for what he

11 was viewing as a very high risk program.

12 Q. And how did that -- why did you think

13 that that would impact Dr. Leiden's decision to

14 halt the Phase I clinical trial of ABT-518?

15 A. Because if he thought it was high risk

16 and the risk was lower, that would be desirable.

17 Q. Did you believe at the time that

18 Abbott's decision to halt the Phase I clinical

19 trial of ABT-518 could have an effect on Hancock's

20 willingness to enter into the deal?

21 A. I have no idea what Hancock -- I

22 thought at the time I was not part of the

23 negotiation, the signing or the approval.

24 Q. Do you recall anyone within Abbott ever

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1 expressing any concern to you that Abbott's
2 decision to halt the Phase I clinical trial of
3 ABT-518 in March of 2001 could adversely impact
4 Hancock's willingness to enter into the Research
5 Funding Agreement?

6 A. I know people were very disappointed,
7 Dr. Nisen in particular, that this compound that
8 he had worked on for so long was being put on this
9 halted status and Perry was quite disappointed
10 about that. It was not done in the context of
11 Hancock. It was in the context of the Discovery
12 program that he had led for several years and was
13 now responsible for in the form of its development
14 stage.

15 Q. My question is a bit different,
16 Dr. Leonard.

17 Do you recall anyone within Abbott
18 expressing any concern to you or in your presence
19 that Abbott's decision to halt the Phase I
20 clinical trial of ABT-518 in March of 2001 might
21 cause Abbott -- might affect John Hancock's
22 willingness to enter into the Research Funding
23 Agreement?

24 A. I don't recall that being specifically

1 discussed.

2 Q. Do you recall it being generally

3 discussed in any way?

4 A. I had nothing to do with the

5 negotiation and I was not part of what was going

6 on at that time. I don't think I could have even

7 known where they were with respect to signing it.

8 I don't recall.

9 Q. So the answer to my question is, no,

10 you don't recall?

11 A. I don't specifically recall. People

12 were very disappointed that this program couldn't

13 continue based on its medical merits.

14 Q. You say you don't specifically recall.

15 My question is more general than that. And I want

16 to know if you have any recollection as you sit

17 here today of any conversations or communications

18 within Abbott in which anyone expressed concern

19 that Abbott's decision to end the Phase I clinical

20 trial of ABT 518 in March 2001 could somehow

21 impact John Hancock's willingness to enter into

22 the Research Funding Agreement? Do you have any

23 recollections along those lines?

24 A. It's such a general question, there may

1 have been people. I may have heard things. I
2 don't know. My dealings with the clinical team
3 were around the clinical program and what we were
4 studying at that time.

5 Q. You say there may have been -- people
6 may have said things.

7 Do you recall anyone saying anything to
8 that effect back in March of 2001?

9 A. I don't recall specifically recall, no.

10 Q. Do you have a general recollection of
11 someone saying that?

12 A. No. I recall Dr. Nisen being very
13 upset that he had -- this program he had worked on
14 for so long was abruptly halted when he believed
15 that the medical prospects for it were still
16 there.

17 Q. So as you sit here today, you have no
18 recollection of anyone within Abbott expressing
19 such concerns in the March 2001 time frame; is
20 that right?

21 A. I don't recall as I sit here now at
22 this point talking about that.

23 Q. Or hearing anyone talk about it?

24 A. I don't recall.

1 MR. DAVIS: Let me just take two seconds.

2 Let's mark this, please, as the next

3 exhibit.

4 (WHEREUPON, a certain document

5 was marked Leonard Deposition

6 Exhibit No. 5, for identification,

7 as of 11/30/06.)

8 (WHEREUPON, the document was

9 tendered to the witness.)

10 BY MR. DAVIS:

11 Q. Dr. Leonard, you have Exhibit 5 in

12 front of you, which I will represent is a series

13 of e-mails that were produced to John Hancock by

14 Abbott in this litigation.

15 A. Uh-huh.

16 Q. First have you seen any of these

17 e-mails before?

18 A. They look familiar to me.

19 Q. Pardon me?

20 A. They look familiar to me.

21 Q. Now, I believe the chain actually

22 begins -- actually this one is an odd one because

23 there appear to be sort of a mix of dates here,

24 but let me first point your attention --

1 A. They start at the bottom and work up.

2 Q. Correct, except if you look at the last
3 page, there is an e-mail that's dated March 23; do
4 you see that?

5 A. This is not part of the same chain
6 presumably, right?

7 Q. If you look at the second page of
8 Exhibit 5, the e-mail from Mr. Deemer to
9 Dr. Nisen; do you see that?

10 A. I see it.

11 Q. You've seen that e-mail before?

12 A. Yeah, I've seen it before.

13 Q. When did you last see it?

14 A. Yesterday.

15 Q. When is the last time you saw it before
16 yesterday?

17 A. I don't recall specifically.

18 Q. Do you recall generally?

19 A. It may have been at the last deposition
20 I gave.

21 Q. Now, do you recall Mr. Deemer again
22 expressing any concerns back in the March 2001
23 time frame that Abbott's decision to end or to
24 halt the clinical trial of ABT-518 could have been

1 a death nail to the deal with John Hancock?

2 A. I don't know what Dr. Deemer said

3 specifically to Dr. Leiden. I remember speaking

4 to Dr. Leiden about the general medical prospects

5 of the compound and pointing out to him that I

6 believed the compound was still meritorious and

7 should be tested.

8 Q. Did you point out to Dr. Leiden that if

9 Abbott did not change its decision to halt that

10 clinical trial that it might adversely affect the

11 proposed deal with John Hancock?

12 A. I don't recall saying anything like

13 that. I had no negotiation role with Hancock. I

14 didn't know what Hancock was thinking. As a

15 scientist, I spoke on behalf of the medical

16 prospects.

17 Q. Mr. Deemer's e-mail to Dr. Nisen says:

18 "I worked with John to protest that and I

19 understand it's back on track."

20 Do you recall working with Mr. Deemer

21 to protest Abbott's decision to end the Phase I

22 clinical trial of ABT-518 in March of 2001?

23 A. I don't recall doing anything jointly

24 with Phil. I talked to Leiden as I've already

1 described.

2 Q. You were successful in convincing

3 Dr. Leiden to reinstitute the trial?

4 A. We reinstituted the trial, yes.

5 Q. At the time Abbott made the decision to

6 halt the clinical trial of ABT-518, that trial had

7 been funded within Abbott; is that right?

8 A. Yes. I think it was part of our --

9 almost certainly part of our budgetary plan.

10 Q. Sometime after Abbott restarted the

11 Phase I clinical trial of ABT-518, that trial was

12 terminated again; is that right?

13 A. It was subsequently terminated, that's

14 correct.

15 Q. It was subsequently terminated before

16 the trial was over?

17 A. That's correct. It was terminated and

18 the trial became over. They were simultaneous I

19 guess. If you're saying we enrolled fewer

20 patients than was originally intended, that's

21 correct.

22 Q. I could be more exact. Ultimately the

23 Phase I clinical trial of 518 after it was

24 restarted was terminated again before the trial

1 was originally scheduled to end; is that right?

2 A. That is correct.

3 Q. Who made the decision to permanently

4 halt the Phase I clinical trial of ABT-518?

5 A. I think it was a joint assessment of

6 senior management including myself prompted by the

7 deluge of data that had come out from the ASCO

8 trial or ASCO meeting is what I meant to say.

9 Q. As you sit here today, you can't be any

10 more specific with respect to the deluge of data

11 that you received from that ASCO conference; is

12 that right?

13 MR. WEINBERGER: I object to that. He's

14 already been more specific three or four times if

15 you want him to repeat all that, but he's already

16 talked about that.

17 BY MR. DAVIS:

18 Q. Well, please tell me specifically --

19 MR. WEINBERGER: That's not right.

20 MR. DAVIS: Please, please. Let me ask my

21 questions before you object to be them.

22 MR. WEINBERGER: Go ahead. Go ahead.

23 MR. DAVIS: And then you can object and then

24 I am entitled to an answer.

1 A. I see it.

2 Q. First, were you aware in February 2001
3 that Pfizer had previously announced that it was
4 stopping its Phase III trials of its MMPI product
5 Prinomastat in advanced prostate, and I think
6 that's non-small cell lung cancer, because the
7 primary efficacy objectives were not met?

8 A. Presumably I was aware of that.

9 Q. Do you recall as you sit here today
10 being aware of that fact?

11 A. Not specifically. I knew we had some
12 competitor information that we didn't think
13 particularly bore on our program.

14 Q. Do you recall discussing information
15 about Prinomastat at the meeting at which
16 Dr. Leiden instructed Abbott personnel to cease
17 the or to halt the Phase I clinical trial of 518?

18 A. I don't recall specifically. It may
19 well have come up.

20 Q. Further in the same box there is a
21 reference to: "Marimastat development was
22 discontinued on 2/15/01."

23 Do you see that?

24 A. I see that.

1 Q. Were you aware back in February of '01
2 that Marimastat development had been discontinued
3 in that month?

4 A. I don't specifically recall it. I may
5 well have been.

6 Q. Is that something that was discussed
7 with Dr. Leiden at the time that he ordered a halt
8 on the Phase I clinical trial of 518?

9 A. I don't recall specifically. It may
10 well have come up in the meeting.

11 MR. DAVIS: Let's mark this as the next
12 exhibit, please.

13 (WHEREUPON, a certain document
14 was marked Leonard Deposition
15 Exhibit No. 7, for identification,
16 as of 11/30/06.)

17 (WHEREUPON, the document was
18 tendered to the witness.)

19 BY MR. DAVIS:

20 Q. Dr. Leonard, if you would look at this
21 document for a moment, in particular let me direct
22 your attention to the second page of the document,
23 at the first section under Clinical Update.

24 Do you see that?

1 A. I see it.

2 Q. These purport to be MMPI Working Group

3 meeting minutes dated from March 8 of 2001.

4 Do you see that?

5 A. I do.

6 Q. Did you ever participate in any MMPI

7 Working Group meetings?

8 A. I don't recall specifically doing it.

9 We have project teams and I think this particular

10 project team called itself a Working Group. It

11 was an extended group of people that had

12 clinicians, toxicologists, pharmacokinetics,

13 formulation scientists, et cetera, and they would

14 meet to discuss the project. I was typically not

15 a part of any project team, per se.

16 Q. Do you recall that Dr. Nabulsi and

17 Ms. D'Amico were part of that team?

18 A. I would expect them to be. Dr. Nabulsi

19 I believe -- well, Dr. Nabulsi was part of the

20 oncology clinical team and I don't recall his

21 specific role on MMPI. He may well have been

22 involved.

23 Q. Do you have any a recollection of this?

24 A. I don't recall this meeting.

1 Q. This first bullet point under Clinical
2 Update, it says: "A brief summary of the Leiden
3 portfolio review held 3/7/01 to 3/9/01 was
4 presented. Questions were raised regarding
5 ABT-518 since several competitor MMPIs have been
6 discontinued."

7 Do you see that?

8 A. I see it.

9 Q. What were the competitor MMPIs that had
10 been discontinued as of the time that Dr. Leiden
11 had held his portfolio review?

12 A. I don't recall specifically. It may
13 have been the one you just showed me. I know at
14 some point British Biotech ran into problems.
15 That may have been another one that was
16 discontinued. Those programs we thought had
17 little relevance to our own.

18 Q. You recall the discussions with
19 Dr. Leiden about what effect the discontinuation
20 of other competing programs had on 518?

21 A. Again, this was novel pharmacology and
22 there's a series of compounds each with its
23 characteristics and flaws that companies were
24 testing. We believed that the profile of our

1 compound was substantially different and the flaws
2 of the other compounds that preceded us undermined
3 their ability to be a good test of MMPI so we
4 thought that, again, they bore limited relevance
5 to what we were doing.

6 Q. Do you recall the fact that several
7 competitor MMPIs had been discontinued was one of
8 the factors in Dr. Leiden's decision to halt the
9 development of ABT-518 at that time?

10 MR. WEINBERGER: Objection. Calls for
11 speculation.

12 BY THE WITNESS:

13 A. It may well have been.

14 BY MR. DAVIS:

15 Q. Is that consistent with your
16 recollection that that was one of the reasons, one
17 of the things that concerned him at that time?

18 A. I think Dr. Leiden believed it was a
19 high risk program and that may have factored into
20 his assessment.

21 MR. DAVIS: Let's mark this as the next
22 exhibit, please.

23 (WHEREUPON, a certain document
24 was marked Leonard Deposition

1 MR. WEINBERGER: Objection.

2 BY THE WITNESS:

3 A. I don't remember.

4 BY MR. DAVIS:

5 Q. Do you recall that Abbott was planning
6 on spending in excess of a billion dollars of its
7 own money on development of the program compounds
8 at that point in time?

9 MR. WEINBERGER: Objection.

10 BY THE WITNESS:

11 A. I don't remember. We create project
12 plans that are highly speculative at any point in
13 time. The attrition rate is extremely high for
14 development programs from Phase III all the way
15 back to the beginning, and what is imagined at one
16 point in time rarely comes to pass.

17 BY MR. DAVIS:

18 Q. Are you familiar with the terms nominal
19 spending or expected spending?

20 A. Nominal, that's a terminology we use
21 where a specific estimate is put forward as
22 opposed to a probabilistic one.

23 Q. So the nominal estimate would be one
24 that does not take into account some probability

1 of actually spending and the expected spending
2 number is one that would take into account some
3 probability of actually spending the amount
4 budgeted?

5 A. Expected is handicapped by
6 probabilities. We like to say that one thing for
7 sure is that we know that those precise numbers
8 will never be the numbers that it turns out to be
9 in the end because it's impossible to know.

10 Q. Is it fair to say that the expected
11 spending numbers are ones that Abbott comes up
12 with in order to try to get a better estimate of
13 what it likely actually will spend?

14 MR. WEINBERGER: Objection.

15 BY THE WITNESS:

16 A. Estimate is the operative word and is
17 correct. We estimate.

18 BY MR. DAVIS:

19 Q. In your experience at Abbott, does
20 Abbott budget both in terms of nominal spending
21 and expected spending?

22 A. It varies. We will have a very good
23 notion usually of what we are going to spend in
24 any particular month, but because there are so

1 many unanticipated changes dealing with the nature
2 of our work which is experimental by design that
3 the precision with which we make any estimates
4 falls off exceedingly quickly.

5 Q. In the course of your work at Abbott,
6 have you seen documents at Abbott that distinguish
7 between or reference nominal and expected spending
8 on program compounds -- please -- on drug
9 development?

10 A. Sure. We at times and various programs
11 and different circumstances will represent a
12 nominal and expected spend.

13 Q. And if you wanted to find those
14 documents today, where would you look?

15 MR. WEINBERGER: Objection.

16 BY THE WITNESS:

17 A. Most of our probabilistic assessments
18 are collated by our decision support group.

19 BY MR. DAVIS:

20 Q. So you would go to someone within the
21 decision support group?

22 A. Typically, yes.

23 Q. Who is currently in charge the decision
24 support group at Abbott?

1 A. Keith Hendrics.

2 Q. Is the decision support group based in
3 the Chicago area?

4 A. It is.

5 Q. At Abbott Park?

6 A. It is.

7 MR. DAVIS: Let's mark this as the next
8 exhibit.

9 (WHEREUPON, a certain document
10 was marked Leonard Deposition
11 Exhibit No. 10, for identification,
12 as of 11/30/06.)

13 (WHEREUPON, the document was
14 tendered to the witness.)

15 BY MR. DAVIS:

16 Q. Dr. Leonard, you have in front of you
17 Exhibit 10. I'm going to ask you, have you seen
18 this document before?

19 A. I think I saw it at my deposition.

20 Q. In round one?

21 A. Yeah. It looks familiar to me.

22 Q. I think you testified earlier that you
23 recall having a telephone conversation with

24 Mr. Blewitt from Hancock and Dr. Klotz at some

1 point in time before the deal was signed.

2 Do you remember that?

3 A. I did. Yeah.

4 Q. I want to direct your attention

5 specifically to a couple of portions of this

6 document. If you look under -- actually look at

7 the second page, you recall that Mr. Cohen and

8 Mr. Deemer also participated in that call?

9 A. I don't remember Mr. Deemer being

10 there. He may well have been. I do remember

11 Steve Cohen sitting in my office.

12 Q. What did you understand to be the

13 purpose of the telephone call?

14 A. I believe it was Steve Cohen had come

15 to me and said that Hancock, John Hancock

16 personnel, Steve Blewitt, was interested in having

17 some outside assessment, third party assessment of

18 our programs and wanted me to speak to the

19 individual, and I agreed to do that.

20 Q. Did you understand at the time that the

21 interview took place that Hancock had drafts or

22 some form of the descriptive memoranda from

23 Abbott?

24 A. I can't recall exactly what they had.

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1 I know they had information. I don't know what
2 form it was provided to him. It may have been
3 descriptive memoranda. I don't know.

4 Q. Do you recall that versions of the
5 descriptive memoranda were provided to Hancock
6 before the deal was executed?

7 A. That I don't know. I don't remember.

8 Q. Did you keep any notes of your
9 telephone discussion with Mr. Blewitt and
10 Dr. Klotz?

11 A. Not that I know of.

12 Q. How did you prepare for that call?

13 A. I don't recall. I may well have spoken
14 based on my general knowledge of the programs.

15 Q. If you'd look on the page that's Bates
16 numbered ending in 2975, do you see there is a
17 reference to ABT-594?

18 A. I see it.

19 Q. That's a compound that Abbott had under
20 development as of July of 2000; is that right?

21 A. Yes.

22 Q. Do you recall discussing that
23 particular compound with Mr. Blewitt and
24 Dr. Klotz?

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1 A. I don't recall specifically. We may
2 well have spoken about it.

3 Q. Near the bottom of this page it says --
4 you see that there are questions that are listed
5 and those are in italics; do you see that?

6 A. I do.

7 Q. And then there's a response that's in
8 -- not in italics; do you see that?

9 A. I do.

10 Q. Do you recall being asked whether from
11 your descriptive memorandum ABT-594 appears to
12 have a therapeutic window of only two to three?
13 Is this small therapeutic window acceptable?

14 A. I don't remember that specifically. I
15 know we -- it reminds me that we discussed it
16 generally.

17 Q. Do you recall discussing side affects
18 associated with ABT-594 in the course of your
19 conference call?

20 A. I suppose we did since that was quite
21 relevant to the compound.

22 Q. I'm sorry?

23 A. I suppose we did since that was quite
24 relevant to the compound.

1 Q. You say you suppose. Do you have a
2 recollection of doing so?

3 A. I don't recall specifically. I'm
4 looking at what are I guess his notes.

5 Q. Do you recall telling Mr. Blewitt and
6 Dr. Klotz that nausea -- that headache and
7 vomiting were not dangerous side effects?

8 MR. WEINBERGER: Objection.

9 BY THE WITNESS:

10 A. I don't recall saying that
11 specifically. I do recall trying to answer all
12 the questions that they posed to me.

13 BY MR. DAVIS:

14 Q. Do you recall telling Mr. Blewitt and
15 Dr. Klotz that headache, vomiting were minor side
16 effects that appeared to go away over time?

17 A. I don't recall that specifically.

18 Q. You don't deny having said that, you
19 just don't have a recollection?

20 A. I just don't remember. It was a
21 conversation that took place.

22 Q. At this time as of July 2000, did you
23 think that nausea, vomiting associated with
24 ABT-594 were minor side affects?

1 A. Minor in the context of not being

2 dangerous, yes.

3 Q. When you said minor in the context of

4 not being dangerous, did you think they were minor

5 in the context that they might impact Abbott's

6 decision to proceed with the development of

7 ABT-594?

8 A. Toxicity profiles in general are things

9 that we deal with to help us try to find what is

10 the appropriate dose. The fact that therapeutic

11 window referred to suggests that there is

12 toxicities that needed to be addressed,

13 understood, I suspect, given what it says here

14 about nausea and vomiting. I remember being with

15 the program thinking about nausea and vomiting and

16 trying to limit their incidence when patients were

17 exposed to the drug.

18 Q. Did you believe that ABT-594 had a

19 problem with nausea and vomiting as of the summer

20 of 2000?

21 MR. WEINBERGER: Object to the form of the

22 question.

23 BY THE WITNESS:

24 A. I think there were some doses that had

1 a high incidence of nausea and vomiting.

2 BY MR. DAVIS:

3 Q. What were those doses?

4 A. I don't recall. There was a range of
5 doses that if I remember right we set out to test
6 which is typical of any program. In fact, it's a
7 regulatory requirement to establish a dose. One
8 tests ranging from placebo which is a dose of zero
9 all the way up to the highest reasonable dose
10 based on preclinical information and whatever
11 other information, and one defines a therapeutic
12 index, doses that are -- that have unacceptable
13 tolerabilities and efficacy that goes with it, and
14 typically one selects a dose somewhere in the
15 middle that has a best risk-benefit tradeoff.

16 Q. Did you understand in the summer of
17 2000 that patients who took ABT-594 and
18 experienced nausea and vomiting generally saw
19 those side effects go away over time?

20 A. I don't recall the details. I knew
21 that this compound, it's a nicotinic channel
22 modulator, exhibited some of the same pharmacology
23 seen with nicotine which is found in cigarettes
24 that has a well known side effect profile of

1 nausea and vomiting particularly when someone
2 begins smoking.

3 We also knew that smokers tend have
4 those side effects abate and there was reason to
5 believe and I think we had observed in our trials
6 if I remember right that some of that pharmacology
7 appeared to be playing out for this drug as well,
8 so we wanted to explore it further.

9 Q. Meaning that you understood at that
10 time that nausea and vomiting were side effects
11 that tended to go away over time?

12 MR. WEINBERGER: Objection.

13 BY THE WITNESS:

14 A. We had a hypothesis that they may go
15 away under a range of different dosing scenarios
16 which we had not yet explored.

17 MR. DAVIS: Let's mark this as the next
18 exhibit, please.

19 (WHEREUPON, a certain document
20 was marked Leonard Deposition
21 Exhibit No. 11, for identification,
22 as of 11/30/06.)

23 (WHEREUPON, the document was
24 tendered to the witness.)

1 of the agreement?

2 A. No, it didn't matter to me.

3 Q. Did anyone ever ask you for

4 recommendations as to what compounds were to be

5 included within the scope of the agreement?

6 A. None that I specifically recall. It

7 didn't matter to me. Again, for me this was a

8 risk mitigation, risk sharing approach and I think

9 I said earlier I was enthusiastic about this sort

10 of approach for our compounds in general.

11 Q. You recall that in the fall of 2000

12 that Abbott had a Phase II-B clinical trial under

13 way for neuropathic pain involving ABT-594?

14 A. That sounds correct.

15 Q. Were you kept apprised of the status of

16 that trial?

17 A. In a general way.

18 Q. By receiving those status reports or

19 monthly highlights that you recall?

20 A. That and discussions as appropriate.

21 Q. Do you recall who at Abbott was

22 involved in overseeing that clinical trial?

23 A. I know Bruce McCarthy was I believe

24 primarily involved with that. I think I mentioned

1 earlier today I can't remember if his supervisor
2 at that time was Marlene VerLinden or somebody
3 else, but Bruce was most directly involved.

4 Q. Did you ask Dr. McCarthy to keep you up
5 to date on what was going on in that trial?

6 A. In a general way, yes.

7 Q. Did you periodically meet with
8 Dr. McCarthy to discuss among other things the
9 status of that trial?

10 A. On occasion.

11 MR. DAVIS: Let's mark this, please, as the
12 next exhibit.

13 (WHEREUPON, a certain document
14 was marked Leonard Deposition
15 Exhibit No. 13, for identification,
16 as of 11/30/06.)

17 (WHEREUPON, the document was
18 tendered to the witness.)

19 BY MR. DAVIS:

20 Q. Dr. Leonard, you have in front of you
21 what's been marked as Exhibit 13, which is labeled
22 a September 2000 ABT-594 Project Status Report.

23 Do you see that?

24 A. I do.

1 Q. Is it your recollection that you
2 received status reports like this in the fall of
3 2000 regarding ABT-594?

4 A. In a general way, yes.

5 Q. The very first item noted on Page 1
6 under Venture, it says: "Extension of enrollment
7 for Phase II-B Neuropathic Pain through 3/01."

8 Do you see that?

9 A. I see it.

10 Q. Do you recall why it was that Abbott
11 decided to extend enrollment for that trial?

12 A. I don't remember. I think enrollment
13 was going slowly if I recall and this may reflect
14 going beyond some original calendar target, but I
15 don't know.

16 Q. Do you remember learning why it was
17 that enrollment was going slowly with that trial?

18 A. I think we had had a fair number of
19 dropouts and enrollment had slowed down perhaps as
20 a result of that. It may have been that we had
21 insufficient investigators. You go off and make
22 an assessment when you begin a trial and you have
23 some number of chosen sites with an expectation
24 that they will enroll -- each site will enroll

1 some number of patients. They may have been
2 miscalculated. I don't know.

3 Q. When you referenced dropouts, is that
4 the same as premature patient terminations?

5 A. It's synonymous, yes.

6 Q. Do you recall understanding why it was
7 that there were so many dropouts or premature
8 terminations in this trial?

9 MR. WEINBERGER: Objection. That was not his
10 words, that was yours.

11 BY THE WITNESS:

12 A. Could you repeat that?

13 BY MR. DAVIS:

14 Q. Sure. Do you remember understanding or
15 having an understanding as to why it was that they
16 were experiencing so many dropouts as you caused
17 them in this trial?

18 MR. WEINBERGER: Objection.

19 BY THE WITNESS:

20 A. I don't remember specifically. I knew
21 we had nausea and vomiting. I recall that we were
22 doing a dose-ranging study at the time which was
23 to determine the incidence of side affects at a
24 range of doses with the full expectation that

1 there would be doses that would be associated with
2 high levels we knew from our earlier work and then
3 to determine the efficacy they went with each of
4 those different doses and came up with a safety
5 efficacy kind of profile.

6 BY MR. DAVIS:

7 Q. Do you recall any discussions in the
8 fall of 2000 about obtaining or enlisting a
9 patient recruitment firm to assist in the ABT-594
10 trial?

11 A. No. I typically don't get involved in
12 decision like that. Individual teams are
13 responsible for producing enrollment on their
14 programs and they have budgetary and decision
15 latitude to go and execute on the general goals
16 that they have. They may well have done that. It
17 wouldn't be surprising.

18 Q. As you sit here today, though, you
19 don't recall that?

20 A. Not specifically, no.

21 MR. DAVIS: I've got one more exhibit that I
22 want to do and then we'll take break for lunch.
23 Let's mark this, please, as the next exhibit.

24 (WHEREUPON, a certain document

1 proposals from patient recruitment firms; do you
2 see that?

3 A. I see it.

4 Q. It says: "A conclusion reached that
5 hiring a recruitment firm to increase enrollment
6 for study M99-114 was not a viable option at this
7 time."

8 Do you see that?

9 A. I see it.

10 Q. You understand that M99-114 study is
11 the Phase II-B clinical trial for ABT-594?

12 A. It sounds right. I believe that's the
13 case.

14 Q. Did you participate in any decision not
15 to hire a recruiting firm in around November 2000?

16 A. Not that I specifically recall. I
17 suspect that this is the team meeting and they are
18 sharing with me whatever their assessment was.

19 Q. Do you know why it was not deemed to be
20 a viable option?

21 A. I don't know.

22 MR. DAVIS: Let's mark this as the next
23 exhibit, please.

24 (WHEREUPON, a certain document

Leonard, John (Linked) 11/30/2006 9:16:00 AM

1 was marked Leonard Deposition

2 Exhibit No. 16, for identification,

3 as of 11/30/06.)

4 (WHEREUPON, the document was

5 tendered to the witness.)

6 BY MR. DAVIS:

7 Q. Dr. Leonard, have you Exhibit 16 in

8 front of you.

9 Have you seen this document before?

10 A. I don't recall this, and I don't --

11 "Top" Issues, I don't know what this is extracted

12 from.

13 Q. You see it's dated December of 2000 and

14 there is a reference to ABT-594.

15 Do you see that?

16 A. I do.

17 Q. Do you recall preparing documents like

18 this to be passed along to any of your supervisors

19 regarding compounds that were under your area of

20 supervision?

21 A. I don't recall preparing anything

22 called Top Issues. I know we had reports that

23 were evolving at that time, but typically what I

24 prepared to pass on was something called

1 Highlights and it was pros with individual
2 descriptions. It didn't look anything like this
3 particular report.

4 Q. Under ABT-594 it says: "Closing of
5 enrollment on M99-114 as of January 5, 2001; do
6 you see that?

7 A. I do.

8 Q. It says: "It was agreed in December to
9 close enrollment into M99-114, our Painful
10 Diabetic Neuropathy trial, as of January 5, 2001."

11 Did you participate in that decision?

12 A. I was aware of that decision and I know
13 -- I have general recollections of being informed
14 of it.

15 Q. Did you approve the decision?

16 A. I don't remember specific meetings, but
17 I probably did.

18 Q. In order to stop that trial early,
19 would the people at Abbott who were conducting the
20 trial have needed your approval?

21 A. Not always. Teams were put in
22 positions to have a fair degree of autonomy. I
23 think one of the characterizations in your
24 question about stopping it early is -- I'm not

1 sure exactly what you mean by that. The calendar
2 date or what are you asking me?

3 Q. I'll represent to you we already have
4 testimony in this case from Ms. Collicott and
5 Dr. McCarthy that this trial was ended
6 prematurely.

7 MR. WEINBERGER: I don't know what you mean.
8 You better show it to him. This talks about
9 closing enrollment.

10 BY MR. DAVIS:

11 Q. If it's not your understanding that
12 this trial was ended earlier than scheduled, you
13 just simply say so.

14 A. I don't understand the question.
15 Premature to me in my mind refers to a calendar
16 date. If that's what you're asking me, I don't
17 know what the calendar date was for this to be
18 ended.

19 Q. The next sentence on Exhibit 16 states
20 that: "This is two months ahead of our most
21 recent estimate of March 5, 2001 and will include
22 less than our original target of 320 patients."

23 Do you see that?

24 A. I see it.

1 Q. Is that accurate?

2 A. To the best of my knowledge, that's

3 correct.

4 Q. So the trial was stopped at least
5 approximately two months ahead of the date at
6 which it previously had been scheduled to end; is
7 that right?

8 MR. WEINBERGER: Are you talking about
9 enrollment being closed, because that's what the
10 document says that you're reading from?

11 MR. DAVIS: Yes.

12 MR. WEINBERGER: Which is not the words you
13 used.

14 MR. DAVIS: Please don't rephrase my
15 question.

16 MR. WEINBERGER: Don't mischaracterize
17 deliberately documents that don't say what you
18 represent to the witness they say.

19 MR. DAVIS: Please stop prompting the
20 witness.

21 MR. WEINBERGER: I'm not prompting the
22 witness. I'm objecting to your --

23 MR. DAVIS: Then you can object and in the
24 District of Massachusetts the appropriate response

1 is to simply object and not to provide further
2 colloquy on the basis for the objection unless
3 requested.

4 MR. WEINBERGER: In any district I know of
5 you should not tell a witness that the document
6 says X when the words are Y. When you don't do
7 that, we won't have a problem.

8 BY THE WITNESS:

9 A. What is truly closed enrollment ahead
10 of schedule?

11 BY MR. DAVIS:

12 Q. Understanding it would result in the
13 less than the original target of 320 patients?

14 A. Yes.

15 Q. Did you understand that at the time
16 that that was being done?

17 A. I believe so.

18 Q. Do you understand why it was that the
19 decision was made to stop enrollment two months
20 ahead of schedule and at less than the target
21 number of patients?

22 A. My recollection is given where we were
23 in the trial, we thought it was no incremental or
24 very little incremental information we provided by

1 enrolling additional patients.

2 Q. What do you mean "given where we were
3 in the trial?"

4 A. With the number of patients we had
5 already in hand that the contribution of
6 additional patients would contribute very little.

7 Q. Did you have any understanding at that
8 point in time as to what if any information would
9 be garnered from the trial, what the results would
10 be?

11 A. No. The study was blinded.

12 Q. So you had no understanding at that
13 point in time what the results were likely to be
14 from that trial?

15 A. The study was blinded. I don't know
16 the results until we unblinded.

17 Q. What I said was correct. You had no
18 idea?

19 A. The study was blinded and it was
20 impossible for me to know the overall performance
21 of the drug until it was unblinded.

22 Q. I think my question is rather simple.
23 So you had no idea at that point in time as to
24 what the likely results of the study was going to

1 A. I don't understand the question what

2 "no" idea means.

3 Q. You don't understand that phrase?

4 A. I don't understand that phrase.

5 Q. Did you have a belief at the time that

6 the decision was made --

7 MR. DAVIS: Yes. We can go off the record.

8 Why don't we do that.

9 THE VIDEOGRAPHER: Going off the record at

10 1:32 p.m.

11 (WHEREUPON, a recess was had.)

12 THE VIDEOGRAPHER: We're going back on the

13 video record at 1:33 p.m.

14 (WHEREUPON, discussion was had

15 off the record.)

16 MR. DAVIS: I'll just mention for the record

17 that we have removed the back drop because it

18 didn't seem to want to stay where it was supposed

19 to stay.

20 BY MR. DAVIS:

21 Q. Doctor, is it correct that as of the

22 time that the decision was made to close

23 enrollment in the Phase II-B study of 594 two

24 months ahead of schedule that you had no belief or

1 understanding of what the results of that study

2 were likely to be?

3 MR. WEINBERGER: Objection.

4 BY THE WITNESS:

5 A. I really don't understand the question.

6 We embarked on the study with an expectation that

7 there would be activity. We anticipated we would

8 see some of the activity we had seen previously.

9 That was an idea I had.

10 BY MR. DAVIS:

11 Q. Did you have any understanding or

12 belief as to whether or not the results of that

13 study were likely to be adverse?

14 A. I don't know what that means.

15 MR. WEINBERGER: Objection. Go ahead. I'm

16 sorry.

17 BY THE WITNESS:

18 A. I don't know what that question even

19 means.

20 BY MR. DAVIS:

21 Q. Did you have any understanding or

22 belief as to whether the results of that study

23 when they were unblinded were likely to cause

24 Abbott to decide to discontinue development of

1 ABT-594?

2 A. We did a study, again, that was a
3 dose-ranging study to define across a range of
4 doses as required by the Food & Drug
5 Administration to determine an adverse event
6 profile that goes with an efficacy profile. There
7 is by definition an expectation in doing that that
8 one will see adverse events at some doses. It is
9 designed precisely to accomplish that. I expected
10 when we unblinded the results to see an efficacy
11 adverse event profile.

12 MR. DAVIS: Would you reread my question,
13 please.

14 (WHEREUPON, the record was
15 read by the reporter.)

16 BY THE WITNESS:

17 A. Did I expect it would cause us to
18 discontinue ABT-594? No, I didn't know one way or
19 another. We were doing a study to define an
20 adverse event and efficacy profile.

21 MR. DAVIS: Let's mark this as the next
22 exhibit, please.

23 (WHEREUPON, a certain document
24 was marked Leonard Deposition

1 A. I don't know what this is referring to,
2 and I don't know what they were informed of.

3 BY MR. DAVIS:

4 Q. Are you aware of any significant
5 changes in the developmental strategy of ABT-594
6 that occurred in or around late 2000?

7 A. Late 2000? I don't recollect. I mean,
8 we were getting data, doing studies. I believe
9 114 was running at that time. Without having data
10 in hand, it's a little hard to make changes in
11 response to those data. We were trying to define
12 it as I think I said before an efficacy trial that
13 would go -- efficacy and safety profile would go
14 with the various different doses that we were
15 profiling.

16 Q. Doctor, this document refers to a
17 significant change in the developmental strategy.

18 My question is are you aware of any
19 significant change in the developmental strategy
20 of ABT-594 that occurred in the late 2000 time
21 frame?

22 MR. WEINBERGER: He just answered that.

23 Objection.

24 BY THE WITNESS:

1 A. I am not.

2 BY MR. DAVIS:

3 Q. Who within Abbott was empowered as of
4 late 2000 to make changes in the developmental
5 strategy for ABT-594?

6 A. They could have been nominated by the
7 team. They presumably would have been approved by
8 me unless we had rogue teams that I was not aware
9 of, but I didn't write or approve this document.

10 MR. DAVIS: Let's mark this as the next
11 exhibit, please.

12 (WHEREUPON, a certain document
13 was marked Leonard Deposition
14 Exhibit No. 18, for identification,
15 as of 11/30/06.)

16 (WHEREUPON, the document was
17 tendered to the witness.)

18 BY MR. DAVIS:

19 Q. Dr. Leonard, you have what has been
20 marked as Exhibit 18 at your deposition, which
21 looks to be a couple of e-mails from people within
22 Abbott to one another.

23 Do you know a Bryan Cox?

24 A. I know a Bryan Cox. I don't know if

1 discussion?

2 A. None that I recollect.

3 MR. DAVIS: Why don't we break here and see
4 if we can get him that drink.

5 THE VIDEOGRAPHER: We are going off the video
6 record at 2:35 p.m.

7 (WHEREUPON, a recess was had.)

8 THE VIDEOGRAPHER: Going back on the video
9 record at 2:45 p.m.

10 MR. DAVIS: Would you mark this, please, as
11 the next exhibit.

12 (WHEREUPON, a certain document
13 was marked Leonard Deposition
14 Exhibit No. 27, for identification,
15 as of 11/30/06.)

16 (WHEREUPON, the document was
17 tendered to the witness.)

18 BY MR. DAVIS:

19 Q. Dr. Leonard, you have what's been
20 marked as Exhibit 27 in front of you.

21 Have you seen this document before?

22 A. I think I saw it at my last deposition.

23 Q. This is an e-mail from Mr. Deemer to

24 Mr. Blewitt dated March 12, 2001. It says: "John

1 Leonard looked at all of the documents one last
2 time in preparation for execution and noted an
3 oversight on one of the programs."

4 What were all of the documents that you
5 looked at?

6 A. I don't know.

7 Q. You recall, however, being asked to
8 look at all the program documents in preparation
9 for execution of the Research Funding Agreement?

10 A. I don't know what I was given to look
11 at.

12 Q. So it's possible that you didn't look
13 at the descriptive memos for all of the compounds;
14 is that right?

15 A. That's possible. It says all of the
16 documents. I don't know what that is.

17 Q. Then it says on the ABT-518 program, he
18 noted that Phase I was to started on December
19 2000, fourth quarter 2000, but, in fact, did not
20 start until earlier this month.

21 Do you recall noting that?

22 A. I think that's correct. I thought
23 there was a discrepancy. I vaguely remember that.

24 Q. It says: "This pushed the time line

1 back by a quarter throughout but the launch date
2 is not affected and is actually planned one
3 quarter earlier, second quarter '06."
4 Do you see that?
5 A. I do.
6 Q. It says: "Steve, as you know the timing
7 of starting some of these earlier compound studies
8 is related to completing this financing and hence
9 the reason this one got pushed back a little."
10 Do you see that?
11 A. I do.
12 Q. Did Abbott, in fact, delay the
13 commencement of the ABT-518 Phase I clinical trial
14 because it hadn't done a deal with Hancock?
15 A. I really don't remember.
16 Q. Do you recall any discussions within
17 Abbott about delaying that Phase I clinical trial
18 because the deal with Hancock had not been
19 completed?
20 A. I don't recall that. There's a million
21 reasons why studies get delayed. It could be tox
22 work, it could be formulation work, it could be
23 site selection, investigator contracts,
24 institutional review board approval, all of those

1 things could easily explain this.

2 Q. If you take a look at the descriptive
3 memo that's attached to this e-mail, again, it's
4 the descriptive memo for ABT-518.

5 Do you see that?

6 A. I do.

7 Q. If you turn to the fourth page of the
8 descriptive memo under the section entitled
9 Compounds in Development; do you see that?

10 A. So it's page No. 4.

11 Q. 4035.

12 A. I got it.

13 Q. Do you see the section entitled
14 Compounds in Development?

15 A. I do.

16 Q. It says among other things in the last
17 portion of that paragraph: "Companies with
18 compounds in advance clinical development for the
19 treatment of cancer include Agouron/Warner
20 Lambert, Pfizer, British Biotechnology/Schering
21 Plough and BMS, and are listed below."

22 Do you see that?

23 A. I do.

24 Q. Other companies are targeting this

1 mechanism for arthritis and then if you look on
2 the next page you see there is a chart that
3 identifies different compounds and the companies
4 that were developing them; do you see that?

5 A. I do.

6 Q. Now, one of the compounds is Marimastat
7 which is being developed by British
8 Biotechnology/Schering Plough; do you see that?

9 A. I do.

10 Q. Was it true that British Biotechnology
11 and Schering Plough still had Marimastat in
12 advanced clinical development as of March of 2001?

13 A. I don't know.

14 Q. And you see in the same box it says
15 Prinomastat under comments one of the things noted
16 is efficacy data not available; do you see that?

17 A. I see it.

18 Q. Is it true at that there was no
19 efficacy data available to Abbott at that point in
20 time regarding Prinomastat?

21 A. I don't know. It was publicly
22 disclosed what would have been available to us is
23 what was out in the public and I don't know at
24 that time.

1 Q. Did you in reviewing this descriptive
2 memo for 518 make any effort to determine whether
3 the information that was contained in this chart,
4 for example, was accurate as of the date that John
5 Hancock and Abbott entered into the Research
6 Funding Agreement?

7 A. I don't recall independently verifying
8 that. I relied on teams who would go to the
9 scientific meetings, were active in the field, new
10 investigators at other companies.

11 Q. And did you make any effort to
12 determine whether the paragraph titled compounds
13 in development on the prior page was accurate as
14 of the date that John Hancock and Abbott entered
15 into the Research Funding Agreement?

16 A. I did not independently attempt to
17 verify this. I relied on the teams. They knew
18 more about it than I did.

19 Q. I'm sorry. You relied on who?

20 A. The people on the oncology team.

21 Q. Did you ask the people on the oncology
22 team to review the descriptive memo for ABT-518
23 shortly before the agreement was signed between
24 John Hancock and Abbott to ensure the accuracy of

1 that data as of the date the agreement was signed?

2 A. I don't recall.

3 Q. You don't recall doing that?

4 A. I don't recall doing that, no. I don't

5 know if I did or didn't.

6 Q. Dr. Leonard, I'll represent to you that

7 there is no reference in this descriptive memo for

8 ABT-518 to Abbott having decided to halt the

9 Phase I clinical trial of ABT-518 if only

10 temporarily in March of 2001.

11 Were you aware of that fact that that

12 clinical trial had been halted when you reviewed

13 this descriptive memo?

14 A. I don't know when I reviewed the

15 documents so I don't know if I -- well, apparently

16 I looked at 518 because I proposed a change. I

17 have no idea before this was sent when I reviewed

18 those documents.

19 Q. Did you make any effort to inform John

20 Hancock of the fact that Abbott and specifically

21 Dr. Leiden had decided or instructed people within

22 Abbott to halt that clinical trial?

23 MR. WEINBERGER: Objection.

24 BY THE WITNESS:

1 A. I had no direct contact with John

2 Hancock.

3 BY MR. DAVIS:

4 Q. Did you ever instruct Mr. Deemer or

5 anyone else in Abbott to notify Hancock before the

6 Research Funding Agreement was signed that

7 Dr. Leiden had instructed people within Abbott to

8 halt the Phase I clinical trial of ABT-518?

9 A. I don't recall doing that.

10 Q. Is there any reason why you didn't do

11 that?

12 MR. WEINBERGER: Assuming he knew it at the

13 time which is --

14 BY THE WITNESS:

15 A. I don't even know that I knew that

16 Dr. Deemer was going to forward documents to

17 Hancock.

18 BY MR. DAVIS:

19 Q. At the time you were reviewing

20 descriptive memos, you were not aware of the fact

21 that the descriptive memos were going to be passed

22 on to John Hancock?

23 A. No. To be more precise, I don't think

24 I knew when they would be shared.

1 interpretation of this is that it was a team of
2 people engaged in doing something, but you can't
3 tell specifically what it was.

4 Q. But there was a team of people still
5 engaged on an ongoing basis in doing some sort of
6 drug safety support work; is that right?

7 A. Presumably.

8 MR. DAVIS: Let's mark this, please, as the
9 next exhibit.

10 (WHEREUPON, a certain document
11 was marked Leonard Deposition
12 Exhibit No. 28, for identification,
13 as of 11/30/06.)
14 (WHEREUPON, the document was
15 tendered to the witness.)

16 BY MR. DAVIS:

17 Q. Dr. Leonard, you have a copy of the
18 descriptive memo dated February 2001 for ABT-594;
19 do you see that?

20 A. I do.

21 Q. Do you recall reviewing this one at or
22 about the time that you reviewed the ABT-518 memo
23 in preparation for the execution of the Research
24 Funding Agreement by Abbott and Hancock?

1 A. I don't specifically recall. I may

2 have.

3 Q. If you take a look, sir, please, at

4 it's Page 7 of this document there is a reference

5 there to clinical studies; do you see that?

6 A. Clinical or preclinical?

7 Q. No --

8 A. Oh, down on the bottom.

9 Q. The second paragraph in that section

10 states: "A Phase II-B study for neuropathic pain

11 at higher titrated doses of ABT-594 began in April

12 2000 and ends in June 2001."

13 Do you see that?

14 A. I do.

15 Q. That's the same study that which Abbott

16 ended enrollment two months ahead of schedule in

17 January of 2001, correct?

18 A. Okay.

19 Q. You agree with me?

20 A. It should be. I would expect that.

21 Q. It says also here a total of 320

22 patients is anticipated to be included in the

23 study; do you see that?

24 A. I do.

1 Q. As of March 2001, did you anticipate
2 that there would be 320 patients in that Phase
3 II-B study?

4 A. I think we have seen documentation that
5 we expected enrollment to be shut off at 260-some
6 patients and I think that is around the same time
7 frame.

8 Q. So as of March 2001, you no longer
9 anticipated that there would be 320 patients
10 included in that study; is that right?

11 A. I think that's correct, yes.

12 Q. So a statement here certainly as of
13 February 2001 that 320 patients were anticipated
14 to be included in that study would be incorrect;
15 is that right?

16 A. I don't know precisely when we made the
17 change. I don't know precisely when this was
18 written or when it was looked at, but the number
19 did change over time.

20 Q. But this one dated February 2001,
21 correct?

22 A. Okay. Yes. That's what it says, so
23 could you repeat your question?

24 Q. Certainly. At least as of February 1,

1 2001 it was no longer a true statement to say that
2 a total of 320 patients was anticipated to be
3 included in that Phase II-B study of ABT-594; is
4 that right?

5 A. I can't remember when the change was
6 made to 269. When was that change made? We had
7 documents that we looked at before.

8 Q. Enrollment was ended on January 5 of
9 2001?

10 A. Yeah, then it's correct that we
11 expected the number to be different from 320.

12 Q. Do you recall flagging that point
13 around the time that the agreement was signed?

14 A. I don't recall flagging it, no.

15 Q. I don't know if I even saw it.

16 MR. DAVIS: Let's mark this, please, as the
17 next exhibit.

18 (WHEREUPON, a certain document
19 was marked Leonard Deposition
20 Exhibit No. 29, for identification,
21 as of 11/30/06.)

22 (WHEREUPON, the document was
23 tendered to the witness.)

24 BY MR. DAVIS:

1 Abbott in the March April 2001 time frame
2 regarding offering a preemptive plan for
3 development of ABT-518?

4 A. I don't know what that means.

5 Q. Let's mark this, please, as the next
6 exhibit.

7 (WHEREUPON, a certain document
8 was marked Leonard Deposition
9 Exhibit No. 30, for identification,
10 as of 11/30/06.)

11 (WHEREUPON, the document was
12 tendered to the witness.)

13 BY MR. DAVIS:

14 Q. Dr. Leonard, you have Exhibit 30.
15 Would you take a look at this document for a
16 moment and identify it for me, please, if you can.

17 A. It looks like one of the sort of
18 standard portfolio analyses.

19 Q. Portfolio analysis by Abbott?

20 A. Abbott products, what's different about
21 this from -- yeah, Abbott products.

22 Q. What is Abbott products?

23 A. Things that we actively control,
24 choices we have to invest and proceed with.

1 do that; is that right?

2 A. I mean, if something had expected sales
3 of zero it would be foolhardy to proceed.

4 Q. Do you recall attending meetings
5 concerning this portfolio analysis of Abbott's
6 global pharmaceutical development assets?

7 A. I believe this was made available. I
8 can't remember if it was part of the presentation
9 or if it was background reading, but I recall this
10 as being made available as part of our portfolio
11 review around that time frame, yes.

12 Q. Do you recall any discussions
13 concerning ABT-518 in that context?

14 A. As I recall, every single program was
15 presented very, very briefly and the venue I
16 remember was a couple of days set aside where
17 every program team had some limit the period of
18 time called 15, 20 minutes, 30 minutes, I can't
19 remember, but it was like that where they came up
20 and gave summary information on their program so
21 we could see everything altogether.

22 Q. Do you recall any discussions
23 concerning ABT 518 in that context?

24 A. Not specifically -- well, actually I

1 know we discussed 518.

2 Q. What do you recall was discussed?

3 A. I think we -- I can't remember the

4 discussion itself in terms of the presentation

5 other than I think we had at that point data that

6 had become available from the ASCO that we talked

7 about before and I believe it was an executive

8 session after that meeting when we made a decision

9 not to proceed with 518 because of the information

10 that we had learned was so definitive.

11 Q. The information you learned at ASCO was

12 so definitive?

13 A. Correct, which I was I think reviewed

14 there or presented as part of the team's review

15 Q. As best you recall specifically what

16 date was it on which that executive meeting

17 occurred and the decision was made to discontinue

18 development of ABT-518?

19 A. I don't recall.

20 Q. This one Exhibit 30 is dated April 20th

21 and the e-mail that we saw as Exhibit 31 makes

22 reference to that's dated on May 8, 2001.

23 Do those refresh your recollection in

24 any way as to when it was the decision was made to

1 discontinue development of ABT-518?

2 A. As I read the first paragraph here:

3 "Finally last week we presented the consolidated
4 discovery development commercial analysis of the
5 each of the 11 disease areas."

6 If this refers to the meeting that I'm
7 talking about, presumably sometime in early May.

8 MR. DAVIS: Would you mark this please as the
9 next exhibit?

10 (WHEREUPON, a certain document
11 was marked Leonard Deposition
12 Exhibit No. 32, for identification,
13 as of 11/30/06.)
14 (WHEREUPON, the document was
15 tendered to the witness.)

16 BY MR. DAVIS:

17 Q. Dr. Leonard, you have Exhibit 32 in
18 front of you, would you take a moment to read the
19 e-mails here and tell me when you're done, please.

20 I think we already established that you
21 know of Diane D'Amico; she is one of the people
22 listed on these e-mails.

23 Do you recognize any of the other
24 names?

1 far as I was concerned, it was longer a viable
2 compound based on data that became available to
3 us. I don't know what Dr. Nisen shared with his
4 team.

5 Q. Is it accurate that on the basis of
6 that information Abbott decided it didn't want to
7 fund the development of ABT-518 any further?

8 A. It's accurate that based on that
9 information that became available at the ASCO
10 meeting that we chose to terminate the program and
11 abandon it.

12 MR. DAVIS: Let's mark this, please, as the
13 next exhibit.

14 (WHEREUPON, a certain document
15 was marked Leonard Deposition
16 Exhibit No. 35, for identification,
17 as of 11/30/06.)

18 (WHEREUPON, the document was
19 tendered to the witness.)

20 BY MR. DAVIS:

21 Q. Dr. Leonard, would you look at Exhibit
22 35 for a moment and tell me if you've seen this
23 document before?

24 A. It looks like I wrote it.

1 Q. Is this an e-mail that you sent out on
2 or about June 27, 2001?

3 A. Yes.

4 Q. Was this the first time to your
5 knowledge that these people, the recipients of
6 this e-mail, had been notified that these
7 particular development projects had been
8 terminated?

9 A. I would say that it's the first time
10 that they may have all heard directly from me,
11 again, the primary -- if you'll look into the
12 document on the third page, 142, the primary
13 contacts all of whom had been involved in these
14 reviews previously and I would have expected that
15 they would have shared these results well in
16 advance of my e-mail.

17 Q. In the very first paragraph of your
18 e-mail, you state: "As each of you are aware as
19 part of the Abbott Pharmaceuticals development
20 portfolio rationalization, the decision has been
21 made to terminate several development projects
22 effective immediately."

23 What is a portfolio -- development
24 portfolio rationalization?

1 A. Employing a logic to the choices in
2 front of us.

3 Q. Was it different than a standard
4 portfolio review in any way?

5 A. No. I think portfolio management is an
6 ongoing exercise in rationalization on a
7 month-to-month basis.

8 Q. You see that on the third page of this
9 document the page that's Bates numbered ends in
10 4142?

11 A. Yes.

12 Q. The chart there, there are a number of
13 columns, one of which is titled Savings; do you
14 see that?

15 A. Yes.

16 Q. And that's the targeted savings that
17 Abbott hoped to achieve by terminating these
18 particular projects?

19 A. Well, I'd say it a little differently.
20 I think these are the savings that probably were
21 anticipated to be saved based on terminating the
22 program at that particular point in time.

23 Q. How much money did Abbott actually save
24 by terminating ABT-518?

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1 without toxicity so you could achieve higher doses
2 and higher concentrations. It was a series of
3 additional data in the form of combination
4 therapy, mono therapy, and there was information
5 that came out in the form of different stages of
6 the malignancy very early on. My recollection is
7 that all the data that was publicly available had
8 looked at very, very advanced patients and one of
9 the primary questions was whether or not if you
10 had treated earlier you would have a different
11 outcome. I think that information was revealed
12 for the first time at the ASCO meeting.

13 MR. DAVIS: Let's mark this, please, as the
14 next exhibit which should be Exhibit 38.

15 (WHEREUPON, a certain document
16 was marked Leonard Deposition
17 Exhibit No. 38, for identification,
18 as of 11/30/06.)

19 (WHEREUPON, the document was
20 tendered to the witness.)

21 BY MR. DAVIS:

22 Q. Dr. Leonard, you have what has been
23 marked as Exhibit 38. Take a moment to look at
24 that document and then I want to direct your

1 attention to one of the e-mails. Tell me please

2 when you're done reading it.

3 A. I've read it.

4 Q. There's reference with two thirds of

5 the way down on the page to the goal is to review

6 with key PEC members; do you see that?

7 A. Yes.

8 Q. What is PEC?

9 A. Pharmaceutical executive committee.

10 Q. Were you a member or are you a member

11 of the pharmaceutical executive committee?

12 A. I have been since its inception.

13 Q. What is the pharmaceutical executive

14 committee?

15 A. This was Dr. Leiden's meeting where key

16 programs, key decision points would be reviewed.

17 I don't recall when the PEC began. Dr. Leiden

18 created it I think sometime in 2001, but I don't

19 remember when.

20 Q. You're currently a member of PEC?

21 A. I am.

22 Q. Is the name of that organization

23 changed at any point in time since it was created?

24 A. No.

1 Q. How frequently does it meet?

2 A. Typically monthly.

3 Q. Are there minutes kept of PEC meetings?

4 A. Recently there have. Early on there

5 were not.

6 Q. When you say early on, with a time

7 frame do you mean?

8 A. I think we've had minutes kept for the

9 last year and a half or so.

10 Q. Prior to that there were no minutes or

11 records of meetings?

12 A. That was not the standard practice, no.

13 Q. You say it was not the standard

14 practice.

15 Does that mean that on occasion they

16 were kept, other occasions they were not?

17 A. There was no scribe at the meeting.

18 Q. How were the decisions of the PEC

19 recorded back when there were no minutes kept?

20 A. The responsible person would be charged

21 with communicating whatever the decision was to

22 his or her group.

23 Q. Was it the PEC that made the decision

24 to discontinue development of ABT-594?

1 A. I don't remember. It may well have
2 been that review that we've looked at previously,
3 I've lost it here. There was a 594 -- here, I'm
4 sorry, No. 36 could well have been a PEC document.

5 Q. Do you remember when it was that Abbott
6 decided to discontinue development of ABT-594?

7 A. Not precisely. No.

8 Q. Do you recall participating in the
9 decision to terminate development of ABT-594?

10 A. Generally I remember talking about it
11 and deciding to discontinue. I just don't
12 remember exactly when that took place.

13 Q. The side effects including the nausea
14 and the vomiting and the dizziness were observed
15 in the Phase II-B clinical trial of ABT-594 play a
16 role in Abbott's decision to terminate the
17 development of that compound?

18 A. It played a role among other things. I
19 recall that we had conducted a Phase II-B study.
20 Again, the purpose of that is to collect both
21 efficacy and tolerability at a range of different
22 doses and once that study was unblinded and we saw
23 the results, we were able to see what the
24 performance characteristics of the drug were at

1 the doses we tested. The conclusion as I recall
2 was that although there was some efficacy there,
3 the side effect profile that came with that would
4 make that compound unattractive in the
5 marketplace.

6 Q. When you say the side affect profile,
7 you mean among other things, the nausea and the
8 vomiting and the dizziness; is that right?

9 A. That's correct.

10 Q. Did PEC play a role in the decision to
11 terminate ABT-518?

12 A. Not formal list particularly because I
13 think as I recall that was made at the not truly
14 PEC meeting, but this portfolio review that was
15 taking place shortly after the acquisition of
16 Knoll.

17 Q. Were there any notes kept of that
18 portfolio review or portfolio rationalization
19 process that was undertaken in April or May of
20 2001?

21 A. Not by me.

22 Q. Do you know whether anyone else kept
23 any records or minutes of those meetings?

24 A. I don't know if there were formal

1 rarely if ever including me that if that potential
2 licensee wants some clarification of some of the
3 data those people from the project team will go
4 and answer those questions.

5 Q. Have you ever participated in any
6 efforts to out license ABT-518?

7 A. None that I recall.

8 Q. Have you ever participated in any
9 activities by Abbott to in license any compounds?

10 A. Yes.

11 Q. Have you ever done any due diligence or
12 participated in any due diligence by Abbott with
13 respect to compounds that Abbott proposes to in
14 license?

15 A. Not so much compounds, but we have
16 purchased some companies. I have been involved in
17 diligence on those companies.

18 Q. On those occasions where you have
19 participated in diligence, one of the things you
20 have looked at or wanted to examine is information
21 regarding clinical trials for those compounds?

22 A. That's a standard part of any --
23 (inaudible).

24 Q. One of the the things you wanted to

1 look at when you were considering licensing a
2 compound or purchasing a company that has
3 pharmaceutical compounds under development is
4 whether any trials were, for example, terminated
5 early and the reasons for those terminations?

6 A. That's information that may be helpful.
7 It may be totally irrelevant.

8 Q. Is that the information that you're
9 interested in looking at?

10 A. Among many many other things.

11 MR. DAVIS: Let's mark this, please, as the
12 next exhibit.

13 (WHEREUPON, a certain document
14 was marked Leonard Deposition
15 Exhibit No. 41, for identification,
16 as of 11/30/06.)

17 (WHEREUPON, the document was
18 tendered to the witness.)

19 BY MR. DAVIS:

20 Q. Dr. Leonard, is this a copy of a memo
21 that you send to Dr. Leiden among others in
22 November 2001?

23 A. It looks like it.

24 Q. Do you recognize it as one?

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1 may achieve a higher therapeutic ratio than what
2 we had seen with 594. One of the things that we
3 were struggling with at that time was to take
4 animals that we tested and find an animal model
5 that would better predict what we were seeing in
6 the human situation.

7 I think we've seen information here
8 previously that we did a lot of this work in
9 rodents. Rats don't vomit and they don't show
10 nausea very well. We look for another animal
11 model that actually was able to vomit which is a
12 ferret and we went back and tested compounds in
13 rodents that could vomit to determine whether or
14 not 202, 594 might be different. We believe that
15 202 was behaving somewhat differently with respect
16 to vomiting in the ferret and when we moved into
17 the human situation we found that that was
18 misleading. It was not accurate.

19 Q. Have you ever of a compound named
20 ABT-894?

21 A. Yes.

22 Q. What is ABT-894?

23 A. ABT-894 is another compound from this
24 series where we again have tried to engineer in

1 characteristics that will permit the product to

2 have a wider therapeutic ratio or index.

3 Q. Is ABT-894 still under development by

4 Abbott?

5 A. It is in clinical trials now.

6 Q. What are the status of those clinical

7 trials if you know?

8 A. Actually we'll be reviewing it in the

9 next month.

10 Q. So the trial is over? Is enrollment in

11 the trial ended?

12 A. I'll find out next month the way -- I

13 think there is a couple of things that have been

14 going on. Were we were a looking for data tied to

15 a very specific multiple dose study with across

16 over design. I was told that in the last couple

17 of weeks it was unblinded and that data will be

18 presented next month. I'll see it then.

19 Q. What phase was that trial?

20 A. We are still calling that Phase I.

21 Q. Where was that trial conducted?

22 A. I think it was hear in the U.S.

23 Q. Is ABT-894 a follow on or a back up to

24 ABT-594?

1 A. I would consider it a follow on.

2 MR. DAVIS: Let's mark this, please, as the
3 next exhibit.

4 (WHEREUPON, a certain document
5 was marked Leonard Deposition
6 Exhibit No. 49, for identification,
7 as of 11/30/06.)

8 (WHEREUPON, the document was
9 tendered to the witness.)

10 MR. WEINBERGER: Brian, are we close to done?

11 MR. DAVIS: Why don't we do this one and I
12 will take a couple of minutes and see if there is
13 anything else I need to ask him.

14 Do you have questions for him?

15 BY MR. DAVIS:

16 Q. Dr. Leonard --

17 MR. WEINBERGER: Actually I have got a whole
18 series of questions on the 773.

19 MR. DAVIS: No, please ask them. Somebody
20 ought to be able to ask him questions about 773.

21 BY MR. DAVIS:

22 Q. Dr. Leonard, do you have Exhibit 49 in
23 front of you?

24 A. I do.

1 responsibilities.

2 MR. DAVIS: Why don't we take a break now and

3 I'll see if I have any further questions?

4 MR. WEINBERGER: Okay.

5 THE VIDEOGRAPHER: Going off the video record

6 at 4:53 p.m.

7 (WHEREUPON, a recess was had.)

8 THE VIDEOGRAPHER: We're going back on the

9 video record at 4:59 p.m.

10 BY MR. DAVIS:

11 Q. Dr. Leonard, did you ever tell

12 Mr. Blewitt or Dr. Klotz or anyone associated with

13 Hancock before the Research Funding Agreement was

14 executed that Abbott had ended the Phase II-B

15 clinical trial, ended enrollment in the Phase II-B

16 clinical trial of ABT-594 two months early?

17 A. I don't recall doing that or not. I

18 don't remember.

19 Q. Do you recall any discussions with

20 anyone at Abbott has to whether that information

21 ought to be conveyed to Hancock in advance of the

22 execution of the agreement?

23 A. Don't remember any discussions like

24 that.

1 Q. You don't recall any?

2 A. I don't.

3 Q. You recall any discussions at all
4 within Abbott before the execution of the
5 agreement regarding whether any new information
6 ought to be provided to John Hancock?

7 A. New information about what?

8 Q. About the status of the compounds.

9 A. About the status of the compounds, I
10 don't remember any particular discussions about
11 that. I think we believed we were conveying
12 information appropriately as we understood it.
13 That was the practice and the expectation
14 throughout the program.

15 Q. That's your understanding was based on
16 the notion that you were supposed to provide
17 generalized information in the descriptive memos,
18 correct?

19 A. Could you repeat that? I didn't hear.

20 MR. WEINBERGER: I was going to have the same
21 request. I couldn't hear the question.

22 BY MR. DAVIS:

23 Q. Sure. Your understanding was that the
24 descriptive memos were intended to provide John

Leonard, M.D., John M. (Vol. 2) (Linked) 6/1/2007 1:11:00 PM

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3 JOHN HANCOCK LIFE INSURANCE)
4 COMPANY, JOHN HANCOCK VARIABLE)
5 LIFE INSURANCE COMPANY AND) No. 05-11150-DPW
6 MANULIFE INSURANCE COMPANY)
7 (f/k/a INVESTORS PARTNER)
8 INSURANCE COMPANY),)
9 Plaintiffs,)
10 -vs-)
11 ABBOTT LABORATORIES,)
12 Defendant.)

13

14 HIGHLY CONFIDENTIAL

15

16 June 1, 2007

17 1:11 p.m.

18

19 The videotaped deposition of JOHN M.
20 LEONARD, M.D. resumed pursuant to adjournment at
21 Suite 1300, Two North LaSalle, Chicago, Illinois.

22

23

24

1 Laboratories and the witness.

2 MR. DAVIS: All set? I think he's -- he was

3 sworn previously.

4 MR. PHILLIPS: That's fine with me.

5 JOHN M. LEONARD, M.D.,

6 called as a witness herein, having been previously

7 duly sworn and having testified, was examined and

8 testified further as follows:

9 EXAMINATION (Resumed)

10 BY MR. DAVIS:

11 Q. Doctor, you understand you're still

12 under oath?

13 A. I do.

14 Q. Dr. Leonard, welcome back.

15 A. Thank you.

16 Q. I know that you're as pleased to be here

17 as I am.

18 First let me ask you: Did you prepare

19 for your deposition here today?

20 A. I did.

21 Q. How did you do that?

22 A. I reviewed some documents with counsel.

23 Q. Anything else?

24 A. For some of the matters that we'll

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1 Q. Did you ever have any discussions with
2 anyone at Abbott in the, say, 2000-2001 time frame
3 in which personnel within Abbott expressed concern
4 about the fact that Dr. Leiden had indicated that he
5 believed that ABT-594 had questionable viability?

6 A. No.

7 Q. You never heard that?

8 A. I don't recollect that. Again, as I
9 said, this is an unusual representation.

10 MR. DAVIS: Let's go off the record for two
11 seconds.

12 THE VIDEOGRAPHER: Going off the video record
13 at 1:21 p.m.

14 (WHEREUPON, a recess was had.)

15 THE VIDEOGRAPHER: Going back on the video
16 record at 1:22 p.m.

17 MR. DAVIS: I think we previously marked this
18 but I'm going to mark it again, so why don't we mark
19 this as Exhibit 45. I do have an extra copy of that
20 one.

21 (WHEREUPON, a certain document was

22 marked Leonard Deposition Exhibit

23 No. 45, for identification, as of

24 06-01-2007.)

1 BY MR. DAVIS:

2 Q. Dr. Leonard, you've seen this document

3 before, Exhibit 45?

4 A. I saw it today.

5 Q. Had you seen it previous to today?

6 A. I don't remember.

7 Q. It appears to be a memo from Dr. Leiden

8 to you, among others, summarizing a -- is that a

9 Pharmaceutical Executive Committee meeting?

10 A. That's correct.

11 Q. Dating from December 10, '01. Did you

12 attend that meeting?

13 A. I don't remember if I was in that

14 meeting.

15 Q. Do you recall attending a meeting in

16 which the Pharmaceutical Executive Committee decided

17 to recommend that Abbott cease or put a hold on

18 development of ABT-773?

19 A. I have a general recollection of that.

20 Q. What do you recall was the discussion at

21 that meeting about 773?

22 A. A very general recollection of clinical

23 data that we had accumulated at that time and

24 discussion of information that was emerging with

1 respect to, in particular, Ketek, a competitive
2 antibiotic that had had gone to an FDA advisory
3 committee meeting sometime earlier in the year, and
4 we thought that it had information that bore on our
5 own program.

6 Q. Do you recall any discussion at that PEC
7 meeting about QT issues?

8 A. I don't remember.

9 Q. Do you recall any discussion at that PEC
10 meeting about dosing issues pertaining to 773?

11 A. I don't remember.

12 (WHEREUPON, Mr. Peter Witty left the
13 deposition proceedings.)

14 BY MR. DAVIS:

15 Q. Do you recall any discussion at that PEC
16 meeting about liver toxicity issues concerning 773?

17 A. I don't remember.

18 Q. Now, the second page of this document at
19 the very top of the page says, "The team is to
20 prepare a 30-minute presentation for Miles White
21 which summarizes the issues and presents the
22 recommendations. Should take place in
23 December 2001."

24 Did I read that correctly?

1 A. You did.

2 Q. Did such a meeting or such a

3 presentation for Mr. White ever take place?

4 A. I remember there was a meeting with

5 Miles. I don't remember exactly when it took place.

6 Q. A meeting with Mr. White regarding 773?

7 A. That's my recollection.

8 Q. Did you attend that meeting?

9 A. I think I was there.

10 Q. Was there -- do you recall whether there
11 was a presentation made to Mr. Miles at that time?

12 MR. PHILLIPS: Mr. White.

13 BY THE WITNESS:

14 A. Mr. White.

15 BY MR. DAVIS:

16 Q. I'm sorry. Mr. White.

17 A. I don't remember specifically what was
18 presented. I know we discussed 773.

19 Q. Did you participate in putting together
20 a presentation for Mr. White?

21 A. I don't believe I assembled any slides
22 in preparation for that meeting. I don't recollect
23 doing so.

24 Q. How long after the PEC meeting did the

1 Q. Dr. Leonard, would you look for a moment
2 at Exhibit 64, and in particular the first two pages
3 of Exhibit 46, and tell me if you recall seeing
4 these e-mails before.

5 A. I don't remember this e-mail. My name
6 is on it and I wrote it. Or I forwarded it at
7 least.

8 (WHEREUPON, Mr. Peter Witty entered the
9 deposition proceedings.)

10 BY MR. DAVIS:

11 Q. Did you -- there is an e-mail that
12 appears about midway through the first page of
13 Exhibit 46. It appears to be an e-mail from you to
14 Eugene Sun dated 12/14/01. Do you recall that?

15 A. I do.

16 Q. Do you recall writing that e-mail?

17 A. I don't.

18 Q. Did you participate in trying to
19 arrange, schedule the meeting with Mr. White
20 regarding 773?

21 A. I didn't.

22 Q. What do you recall was said in the
23 course of the meeting with Mr. White regarding 773?

24 A. I don't remember the details of the

1 meeting other than a general representation of where
2 we were with the program and our assessment that the
3 product was failing to meet its intended target
4 product profile.

5 Q. The -- your assessment was coupled with
6 a recommendation, correct?

7 A. I believe we had put the program on hold
8 at that time. And I don't remember exactly what we
9 said to him with respect to going forward after
10 that.

11 MR. DAVIS: Let's mark this as the next
12 exhibit, please. Exhibit 47.

13 (WHEREUPON, a certain document was
14 marked Leonard Deposition Exhibit
15 No. 47, for identification, as of
16 06-01-2007.)

17 BY MR. DAVIS:

18 Q. Dr. Leonard, you have what's been marked
19 as Exhibit 47. Would you look at this document for
20 a moment, please, and tell me if you recall seeing
21 this before.

22 MR. PHILLIPS: Brian, you asked that question
23 without excluding communications with counsel,
24 showing counsel, and I've allowed the witness to

1 prepared the document.

2 Q. As you sit here today do you deny that

3 you played any role in preparing the document?

4 A. No, I don't deny, I just don't remember.

5 Q. Do you recall seeing drafts of a memo to

6 Mr. White concerning 773?

7 A. I believe I looked at this document at

8 some point in time, I just don't remember.

9 Q. Did you provide input on the memo that

10 was to go to Mr. White regarding 773?

11 A. Probably if this was sent to me I

12 responded. I don't remember what I said.

13 Q. You don't recall any specific comments

14 or input that you had regarding that memo?

15 A. I don't.

16 MR. DAVIS: Let's mark this as the next

17 exhibit, please. Exhibit 48.

18 (WHEREUPON, a certain document was

19 marked Leonard Deposition Exhibit

20 No. 48, for identification, as of

21 06-01-2007.)

22 BY MR. DAVIS:

23 Q. Dr. Leonard, you have what's been marked

24 as Exhibit 48. Would you look at this document for

1 a moment and tell me if you've seen it before.

2 A. I saw some of these slides earlier

3 today.

4 Q. Do you recall participating in the

5 preparation of some -- a slide presentation for

6 Mr. White concerning 773?

7 A. I don't remember how we reviewed these

8 slides. I believe they were prepared by

9 Dr. Bukofzer.

10 Q. Do you recall reviewing them before they

11 were seen by Mr. White?

12 MR. PHILLIPS: Objection, assumes facts not in

13 the record.

14 BY THE WITNESS:

15 A. They were sent to me. I may have looked

16 at them. I would expect that I did. I don't

17 remember doing so.

18 BY MR. DAVIS:

19 Q. Do you recall the preparation of a

20 presentation for Mr. White that was not then used in

21 the course of the meeting with Mr. White regarding

22 773?

23 A. I don't -- I don't recall that, no.

24 Q. Would you look for a moment, please, at

1 the page of Exhibit 48 that -- again, do you

2 remember these little Bates stamp numbers in the

3 lower right-hand corner?

4 A. Sure.

5 Q. This one ends in 0392.

6 A. Got it.

7 Q. Would you look at that page for a

8 moment, and particularly the bulleted points on the

9 top of the page, and then tell me, please, when

10 you're done reading.

11 A. The bulleted points, the bolded ones you

12 mean?

13 Q. Yes.

14 A. Okay.

15 Okay.

16 Q. Is the information stated there, was it

17 accurate as of the time that these slides were

18 prepared back in, say, early 2002?

19 MR. PHILLIPS: Objection, lack of foundation.

20 BY THE WITNESS:

21 A. I have no reason to believe it wasn't

22 accurate.

23 BY MR. DAVIS:

24 Q. Do you recall that Abbott had no

1 pediatric development plan for 773?

2 A. I don't recall that specifically, no.

3 Q. Do you have any reason to believe that

4 it's not true that Abbott didn't have a -- let me

5 give you a clearer question.

6 Do you have any reason to believe that

7 the statement that Abbott had no pediatric

8 development plan was untrue at the time that this

9 document was prepared?

10 A. I actually do have reason to believe

11 it's untrue. There may have been no activity

12 underway, but that doesn't mean we didn't have a

13 plan to carry it out as part of an overall

14 development plan.

15 Q. Did you ever see a pediatric development

16 plan for 773?

17 MR. PHILLIPS: Objection, vague.

18 BY THE WITNESS:

19 A. I don't remember.

20 BY MR. DAVIS:

21 Q. So as you sit here today you don't

22 recall ever seeing a pediatric development plan for

23 773?

24 A. I don't. Although I would say as a

1 had been done and did not confirm the findings from
2 that first Phase I work.

3 MR. DAVIS: Let's mark this as the next
4 exhibit, please. We're up to 49.

5 (WHEREUPON, a certain document was
6 marked Leonard Deposition Exhibit
7 No. 49, for identification, as of
8 06-01-2007.)

9 BY MR. DAVIS:

10 Q. Dr. Leonard, you have what's been marked
11 as Exhibit 49. Is this a copy of a memo that you
12 and Dr. Leiden sent to Mr. White on or about
13 January 17, 2002?

14 A. My name is on the memo, yes.

15 Q. Do you have a recollection of sending
16 this memo to Mr. White?

17 A. Generally speaking, yes.

18 Q. Was the information contained in the
19 memo that you sent to Mr. White truthful and
20 accurate as of the time the memo was prepared?

21 A. As far as I know.

22 Q. So the statements that were made to
23 Mr. White in this memo were truthful statements,
24 correct?

1 A. I believe so.

2 Q. Now, if you look, for example, on the
3 second page of the document under Unresolved
4 Potential Safety Issues. Do you see that?

5 A. I see it.

6 Q. Is it true that one of the reasons why
7 Abbott's PEC -- actually, let me go back for a
8 moment.

9 If you take a look at the Page 1 of
10 Exhibit 49, the very first paragraph of the memo
11 states that "On December 10, the Pharmaceutical
12 Executive Committee," that's the PEC, correct?

13 A. That is correct.

14 Q. "Met to review the development status of
15 ABT-773, our ketolide antibiotic in clinical
16 development for respiratory tract infections. Based
17 on the data reviewed at the meeting, the Committee
18 recommends suspending further development and
19 initiating efforts to out license the compound."
20 Stop there.

21 Does that accurately reflect the
22 recommendation that the PEC made to Mr. White
23 concerning 773?

24 A. That is my recollection.

1 BY MR. DAVIS:

2 Q. Has Abbott aggressively attempted to
3 outlicense ABT-518?

4 MR. PHILLIPS: Object to the form.

5 BY THE WITNESS:

6 A. I don't know what's been done with
7 respect to that. I'm not part of that process.

8 BY MR. DAVIS:

9 Q. Did you ever communicate the PEC's
10 recommendation from December of '01 that Abbott
11 suspend development of 773 to John Hancock?

12 MR. PHILLIPS: I'm sorry. Excuse me just a
13 second.

14 Would you please read the question. I'm
15 not sure I heard that correctly.

16 (WHEREUPON, the record was read by the
17 reporter as requested.)

18 BY THE WITNESS:

19 A. The "you" is me or the "you" is Abbott
20 Laboratories?

21 BY MR. DAVIS:

22 Q. The you is you, John Leonard.

23 A. Yeah. I don't remember.

24 MR. DAVIS: Would you mark this as the next

1 exhibit. I think we're up to 50.

2 (WHEREUPON, a certain document was

3 marked Leonard Deposition Exhibit

4 No. 50, for identification, as of

5 06-01-2007.)

6 MR. PHILLIPS: The document I have is already

7 marked as Leonard 47.

8 MR. DAVIS: That's right.

9 MR. PHILLIPS: Did you want to mark it again?

10 MR. DAVIS: I don't think it's 47 because --

11 MR. PHILLIPS: It looks like it to me. I

12 don't have any care. If you want to --

13 MR. DAVIS: Why don't we just mark it again.

14 MR. PHILLIPS: That's fine.

15 MR. DAVIS: That way we can be absolutely

16 sure.

17 MR. PHILLIPS: Okay. Is this 50 then?

18 MR. DAVIS: This will be 50.

19 Actually, a judge I used to try cases in

20 front of in Boston you didn't have to mark exhibits

21 sequentially. As long as they had different

22 numbers, not a problem. So you'd have Exhibit 1,

23 4000, Exhibit B. He was just fine with that.

24 BY MR. DAVIS:

1 Q. Dr. Leonard, you have in front of you
2 what's been marked as Exhibit 50. Would you look at
3 this document for a moment and tell me if you've
4 seen it before, please.

5 A. I saw it earlier today.

6 Q. Is this -- does this document contain a
7 series of e-mail that you exchanged with Dr. Leiden
8 back in approximately April of 2002?

9 MR. PHILLIPS: I'll just note for the record
10 that the e-mail at the top appears not to be with
11 Mr. Leiden, Dr. Leiden.

12 BY MR. DAVIS:

13 Q. Okay. Well, let's start -- I think the
14 first one in time, if I'm correct.

15 (WHEREUPON, there was a short
16 interruption.)

17 BY MR. DAVIS:

18 Q. The first e-mail in time appears to be
19 the one that actually begins on the bottom of Page 1
20 and goes on to the top of Page 2. It's an e-mail
21 from you to Dr. Leiden dated 4/15/02 at 7:55 a.m.
22 Do I have that correct?

23 A. I'm sorry. Could you repeat that. I
24 apologize.

1 Q. In terms of timing of these e-mails, it
2 appears that the first one in order of time would be
3 the e-mail that begins at the very bottom --

4 A. On the second page.

5 Q. I think the first part is actually on
6 the bottom of Page 1 and it goes on to the top of
7 Page 2.

8 A. Right.

9 Q. It appears to be an e-mail from you to
10 Dr. Leiden that you sent on April 15, 2002, at 7:55
11 a.m. Do you see that?

12 A. That's correct.

13 Q. Did you send that e-mail to Dr. Leiden?

14 A. I believe so, yes.

15 Q. And why were you asking him about how
16 you should handle the 773 communication with John
17 Hancock?

18 A. Presumably because we had to give an
19 update on the status of the program and I wanted to
20 know what information he wanted to convey to Hank,
21 to John Hancock.

22 Q. Now, Dr. Leiden responded to you the
23 same day; is that right?

24 A. Looks that way, yes.

1 Q. Do you recall receiving this e-mail back
2 from Dr. Leiden, the one that appears in the middle
3 of Page 50?

4 A. It looks familiar.

5 Q. So you do recall it?

6 A. I think so, yes.

7 Q. Dr. Leiden told you, he said, "I think
8 we should tell them that we are, 1, reviewing the
9 Ketek situation re size of safety database; 2,
10 carrying out additional Phase I studies of QT and
11 hepatotoxicity at request of FDA to assess class
12 effects of ketolides; 3, analyzing existing Phase II
13 and Phase III results for impact on label and market
14 opportunity."

15 Do you see that?

16 A. I do.

17 Q. And then Dr. Leiden also said, "That we
18 expect this analysis to be complete by June, July
19 and at that point we will be in a position to make a
20 decision on if and how to proceed with additional
21 Phase III development."

22 Do you see that?

23 A. I do.

24 Q. "We will keep them in the loop as our

1 analysis proceeds." Correct?

2 A. Yes.

3 Q. Is that the information that was

4 conveyed to John Hancock, to your knowledge?

5 MR. PHILLIPS: Objection, lack of foundation.

6 BY THE WITNESS:

7 A. I don't know. I mean, presumably there

8 is -- we had written communication with Hancock, and

9 we should look at that to see what was actually

10 conveyed.

11 BY MR. DAVIS:

12 Q. Now, at the time that you had this

13 e-mail exchange with Dr. Leiden you knew that

14 Abbott's PEC had recommended that Abbott suspend

15 further development of 773, right?

16 A. The PEC did, yes.

17 Q. And you were a member of the PEC?

18 A. Yes.

19 Q. Did you recommend to Dr. Leiden that

20 Abbott inform John Hancock that Abbott had --

21 Abbott's PEC had recommended that they suspend

22 development of 773?

23 A. I don't remember recommending anything

24 to him. I think I asked him what he wanted conveyed

1 to Hancock.

2 Q. Did you ask him why you shouldn't tell

3 Hancock that Abbott had recommended -- or that

4 Abbott's PEC had recommended suspending development

5 of 773?

6 A. I don't recollect asking him that.

7 Q. Why not?

8 MR. PHILLIPS: Why doesn't he remember?

9 Objection, vague.

10 BY MR. DAVIS:

11 Q. Why didn't you do that?

12 A. I asked him what he wanted us to convey,

13 and he as my supervisor gave me this and here is the

14 response.

15 Q. Did you --

16 A. I don't think this is inconsistent with

17 what we were doing, by the way.

18 Q. Do you think that this tells Abbott --

19 do you think that the information that Dr. Leiden

20 instructed you to convey to Hancock fairly and

21 accurately depicted the status of ABT-773 within

22 Abbott at that time?

23 A. I don't know what all of the

24 communications to Hancock were, verbal, written or

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1 otherwise. I do know that we were reviewing the
2 Ketek -- reviewing the product in the context of the
3 Ketek situation, we had all kinds of meetings to
4 that effect. I do know that we were, as I recall,
5 carrying out additional studies, some of those were
6 ongoing. And I do know that we were making a
7 determination with respect to where we were going to
8 go with antibiotics in general. I don't think we
9 had made a final decision.

10 Q. My question is a little bit different,
11 though, Dr. Leonard. Do you believe that the
12 information that Dr. Leiden instructed you to pass
13 along to Hancock fairly and accurately described the
14 true status of ABT-773 within Abbott at the time --
15 at that time, in April of '02?

16 MR. PHILLIPS: Objection, asked and answered.

17 BY THE WITNESS:

18 A. Dr. Leiden was chairman of the PEC.
19 I've no idea what he wanted ultimately to do with
20 the compound. It was a PEC recommendation, and I
21 would have to defer to Dr. Leiden in how he felt at
22 that time as to what the ultimate disposition of the
23 compound was going to be in his mind.

24 BY MR. DAVIS:

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1 Q. But I'm not asking what Dr. Leiden was
2 thinking, Dr. Leonard. I'm asking you whether you
3 believe that the information that Dr. Leiden asked
4 you to pass along to Hancock at that point in time
5 as reflected in Exhibit 50 fairly and accurately
6 depicted the true development status of ABT-773
7 within Abbott as of April '02?

8 MR. PHILLIPS: Objection, asked and answered.

9 BY THE WITNESS:

10 A. I don't think it's inaccurate.

11 BY MR. DAVIS:

12 Q. In any way?

13 A. I don't think this information is
14 inaccurate.

15 Q. Do you think it leaves out any material
16 information that you would want to know if you were
17 in John Hancock's shoes?

18 MR. PHILLIPS: Objection, vague.

19 BY THE WITNESS:

20 A. I don't know what Hancock wants to know.

21 BY MR. DAVIS:

22 Q. Do you think Hancock -- if you were an
23 investor in that compound, 773, would you want to
24 know that Abbott's Pharmaceutical Executive

1 Committee had recommended that Abbott suspend
2 development several months prior?

3 MR. PHILLIPS: Objection; incomplete
4 hypothetical, misstates the -- mischaracterizes the
5 testimony, assumes facts not in the record.

6 BY THE WITNESS:

7 A. I think if they wanted to know what was
8 going on every meeting they would have either asked
9 to have a delegate there or have minutes to all
10 those meetings.

11 BY MR. DAVIS:

12 Q. So you don't think if you were an
13 investor you would want to know that information?

14 MR. PHILLIPS: Objection; incomplete
15 hypothetical, calls for speculation.

16 BY THE WITNESS:

17 A. I think that what we as co-investors in
18 this program, I think that's an important thing to
19 remember here, is that the majority of the spend on
20 all these compounds was by Abbott Laboratories, is
21 that we were trying to maximize the value of the
22 compound as we thought we best could.

23 BY MR. DAVIS:

24 Q. Dr. Leonard, please listen to my

1 question. My question is if you were an investor in
2 ABT-773 as of April of '02 would you want to know
3 that Abbott's Pharmaceutical Executive Committee had
4 recommended several months prior that Abbott suspend
5 development of that compound?

6 MR. PHILLIPS: Objection, incomplete
7 hypothetical.

8 BY THE WITNESS:

9 A. I don't know what Hancock wants.

10 BY MR. DAVIS:

11 Q. I'm not asking -- would you reread my
12 question, please.

13 (WHEREUPON, the record was read by the
14 reporter as requested.)

15 MR. PHILLIPS: Objection; incomplete
16 hypothetical, improperly calls for opinion
17 testimony.

18 BY THE WITNESS:

19 A. I've answered that question.

20 BY MR. DAVIS:

21 Q. You don't have any opinion on what you
22 would want to know?

23 A. What I personally? I'm an investor in
24 multiple companies. I don't ask for the results of

1 every single meeting that takes place in all the
2 companies that I hold equity positions in. I mean,
3 I defer to the management to make the best decisions
4 as they see fit. That's the nature of the
5 investment process.
6 Q. If the management of those companies
7 provides a report to you that fails to mention that
8 their executive committee has recommended suspending
9 development of the compound, you would regard that
10 as okay?

11 MR. PHILLIPS: Objection; incomplete
12 hypothetical, calls for speculation, improperly
13 calls for opinion testimony.

14 BY THE WITNESS:

15 A. We were co-investors in 773 with Hancock
16 and we believed we were maximizing the value of the
17 product.

18 BY MR. DAVIS:

19 Q. My question was different, sir.
20 Would you reread my question, please.

21 MR. PHILLIPS: Brian, you're just arguing with
22 the witness.

23 MR. DAVIS: No, I think I'm entitled --

24 MR. PHILLIPS: And you're also improperly

1 your objections.

2 MR. PHILLIPS: That's okay.

3 BY MR. DAVIS:

4 Q. Can you answer that question,

5 Dr. Leonard?

6 BY THE WITNESS:

7 A. I don't think it's improper.

8 MR. DAVIS: Let's mark this as the next

9 exhibit. 51, I think.

10 (WHEREUPON, a certain document was

11 marked Leonard Deposition Exhibit

12 No. 51, for identification, as of

13 06-01-2007.)

14 BY MR. DAVIS:

15 Q. Dr. Leonard, would you look for a moment

16 at Exhibit 51 and tell me if you've seen this

17 document before?

18 A. I saw this earlier today.

19 Q. It is an e-mail from Jeanne Fox to you,

20 among others, at Abbott dated November 2000. Do you

21 recall receiving this e-mail and the attached FDA

22 contact report?

23 A. I don't remember.

24 Q. Do you remember learning back in

1 November 2000 that the FDA had, if only for a period
2 of time, placed a clinical hold on the development
3 of ABT-773?

4 A. I don't believe we were ever actually on
5 clinical hold with the compound. I don't have a
6 recollection that we were. We had, as I recollect,
7 studies underway and continued to enroll them
8 despite this interaction.

9 Q. Do you recall learning back in late 2000
10 that people within Abbott understood that 773 had
11 been placed on -- officially been placed on clinical
12 hold by the FDA?

13 A. Again, I don't remember that. I don't
14 remember being put on clinical hold.

15 Q. Do you recall learning in late 2000 that
16 the FDA was interested in having Abbott conduct some
17 additional dog tox studies pertaining to 773?

18 A. I remember that there was some
19 additional toxicology data requested. I don't
20 remember that it was dog necessarily.

21 Q. Do you recall that the toxicology
22 information that the FDA was requesting was -- had a
23 special emphasis on hepatotoxicity and QT?

24 A. As I read this document, that is what

1 the FDA was looking for. I don't specifically
2 remember those conversations from that time,
3 however.

4 Q. You have a general recollection of being
5 aware back in late 2000 that the FDA had concerns
6 about QT and hepatotoxicity, that's liver tox, right?

7 A. That's correct.

8 Q. That the FDA had concerns about QT and
9 liver tox issues involving 773?

10 MR. PHILLIPS: Objection, assumes facts not in
11 the record.

12 BY THE WITNESS:

13 A. I don't recollect that the FDA ever had
14 concerns about hepatotoxicity or QT in humans beings.

15 As I recall, we had substantial clinical data, in
16 fact exactly to the contrary. There was some
17 questioning from the FDA about the toxicology; that
18 is, the animal studies that had been done and the
19 exposures that had been achieved. It was sort of an
20 odd conversation, as I recall, because the --
21 typically you do animal work to prepare for human
22 work, and in this case the human work exceeded what
23 the animal work was so in some respects we thought
24 it was irrelevant and not particularly helpful.

1 BY MR. DAVIS:

2 Q. Well, did you participate in any of the
3 discussions with FDA regarding 773 in that time
4 period, say late 2000, early 2001?

5 A. I don't remember the time frame
6 specifically. I believe I went to -- I don't know
7 if it was an end of Phase II meeting, but there was
8 an FDA meeting that I did attend. I don't remember
9 being a part of this teleconference.

10 In fact, usually the names are here.

11 Yes, I was not part of this.

12 Q. Do you recall what, if anything, the FDA
13 had to say about either QT or liver tox in the
14 course of that meeting that you attended?

15 A. You're talking about the FDA
16 face-to-face meeting, the one I mentioned?

17 Q. You mentioned a moment ago.

18 A. Right. My recollection is that there
19 was just general questioning about how to
20 demonstrate the absence of a meaningful QT signal.

21 And remember, going back to our earlier
22 discussion here, at that time in general there were
23 questions for all drugs about how to find and
24 demonstrate either the absence of or the presence of

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1 a QT prolongation, which could but doesn't
2 necessarily translate into a safety issue.
3 And in some respects we were caught in
4 the middle here because we had substantial clinical
5 data that we had accumulated, done the way it had
6 always been done, and there were evolving standards
7 taking place at that time. There were questions
8 about how to balance those two differing approaches,
9 which is something that we talked about subsequently
10 for the program.

11 From a hepatotoxicity issue, again my
12 recollection is in the several hundred patients that
13 we had studied, with the exception of two or three,
14 I don't remember the precise number, but two or
15 three Japanese patients under, it was our
16 assessment, a methodologically flawed study there
17 was an absence of any hepatotoxicity.

18 So when we looked at the animal studies,
19 which, again, are done typically to permit human
20 studies, arguing about doing additional animal
21 studies despite having in hand all this human data
22 seemed very odd and irrelevant to us. Nonetheless,
23 they were asking for it.

24 Q. Did you ever have any discussions with

1 anyone at John Hancock about QT or liver toxicity
2 issues involving 773?
3 A. I don't remember.
4 MR. DAVIS: Would you mark this, please, as
5 the next exhibit.
6 (WHEREUPON, a certain document was
7 marked Leonard Deposition Exhibit
8 No. 52, for identification, as of
9 06-01-2007.)
10 THE WITNESS: Pete, could I ask you for a Diet
11 Coke. Could you just put a little ice in there as
12 well.
13 MR. DAVIS: Do you need to take a break?
14 THE WITNESS: I'm okay. Just if he can help
15 me out. Thank you.
16 BY THE WITNESS:
17 A. I'm sorry, did you want me to read a
18 specific thing? I'm sorry.
19 BY MR. DAVIS:
20 Q. Sure, if we've got time right now,
21 please, take a look, please, at Exhibit 52 and tell
22 me if you've seen this document before.
23 A. I don't remember seeing this document.
24 Thank you.

1 Q. It appears to be a memo to Dr. Leiden
2 from Mr. Tyree dated February 13, 2002, and it is
3 titled January 2002 Highlights, and you're one of
4 the cc's. Do you recall receiving documents like
5 this from Tyree in the 2001, 2002 time frame?

6 A. Yeah. As a matter of course monthly
7 highlights were sent out. They were to Jeff, and
8 anyone that Mr. Tyree thought might have an interest
9 in it was typically cc'd.

10 Q. So you do recall receiving it?

11 MR. PHILLIPS: This particular one?

12 BY MR. DAVIS:

13 Q. You recall receiving these types of
14 reports?

15 A. Those types, yes. I don't recall this
16 specific one.

17 Q. You have no reason to doubt that you
18 received this one, though?

19 A. I believe I received it. I don't know
20 if I read it.

21 Q. On the second page of this document,
22 again it is labeled January 2002 Highlights, and let
23 me ask you: Is it your understanding that the
24 document, although it is dated February 13, 2002, it

1 was intended to provide highlights of events that
2 occurred back in January of '02?

3 A. That's correct.

4 Q. Under -- near the bottom of Page 2 of
5 the document under New Initiatives do you see there
6 is a reference to ABT-773 (Partnering)?

7 A. Yes.

8 Q. It says, "Taisho has been informed of
9 the decision to stop the global development of
10 ABT-773 except for the Japan marketplace."

11 Do you see that?

12 A. I do.

13 Q. Who made the decision to stop the global
14 development of ABT-773 except for the Japan
15 marketplace?

16 MR. PHILLIPS: Objection, lack of foundation.

17 BY THE WITNESS:

18 A. I don't know. In fact, I'm not even
19 sure this accurately conveys what was going on. I
20 mean, we had clinical studies that were being
21 conducted. This suggests that no work was taking
22 place, and that's not accurate.

23 BY MR. DAVIS:

24 Q. Well, it doesn't suggest that there is

1 you're done.

2 A. Okay.

3 Q. Actually, this one is pretty simple,

4 Doctor. Were you -- what role did you play in the

5 budgeting process for the various compounds that

6 were under your supervision back in the 2001 --

7 2000, 2001 time frame?

8 A. Yeah. Typically what we would do is

9 have teams lay out an approach for the set of

10 activities that we thought were necessary to gain

11 approval, necessary to understand the compound,

12 necessary to achieve a target product profile, some

13 mix of those things. What I would do is on a -- you

14 know, various times through the course of the year

15 sit down and try to understand those plans,

16 challenge them, and come up with what we regard as a

17 final number which we would then submit to an

18 overall prioritization process that would be

19 reviewed at the level of the PEC.

20 Q. Approximately what time each year would

21 you come up with the plan number that would be

22 submitted to the prioritization process?

23 A. Yeah. It's typically, and I would point

24 out that the 2001 plan was an exception in many,

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1 many respects. But typically what we do is initiate
2 a process in the fall, and we would have a series of
3 reviews and then a final plan completed more or less
4 in the November time frame.

5 2001 I don't know if we ever had a final
6 plan. I believe there was two reasons for that.
7 No. 1 was the recent arrival of Dr. Leiden. This
8 was the first cycle he was going through. But more
9 importantly was the Knoll acquisition that had taken
10 place and many, many things were in flux. The
11 plan -- the planning process typically reflects a
12 lot of certainty going forward, and in this case we
13 had many, many moving parts that we were trying to
14 come to terms with.

15 Q. But there was at some point in time a
16 2001 plan budget?

17 A. I don't know if there was ever a
18 document that was called our final plan. In fact,
19 we were very frustrated that year trying to come up
20 with such a final plan. Revisions and modifications
21 proceeded throughout the first half of the year, as
22 I recall.

23 In fact we by April update, which is the
24 time in early spring where we see how we're doing

1 with the plan, I think we had a difficult time
2 portraying that because the update is versus a plan
3 and we didn't have a final plan to compare it to.

4 Q. Again, you've never seen anything
5 labeled "Final Plan," correct?

6 MR. PHILLIPS: For 2001?

7 BY MR. DAVIS:

8 Q. For 2001.

9 A. Not that I remember.

10 Q. We would go about identifying the final
11 plan by the looking for the words "Final Plan" on
12 it; is that right?

13 A. I think so, yeah.

14 MR. DAVIS: Why don't we take a break for a
15 few minutes.

16 THE VIDEOGRAPHER: Going off the video record
17 at 2:25 p.m.

18 (WHEREUPON, a recess was had.)

19 THE VIDEOGRAPHER: Going back on the video
20 record at 2:36 p.m. at the beginning of Tape No. 2.

21 MR. DAVIS: Would you please mark that as the
22 next exhibit.

23 (WHEREUPON, a certain document was
24 marked Leonard Deposition Exhibit

1 No. 54, for identification, as of

2 06-01-2007.)

3 MR. PHILLIPS: I'm sorry, this is 54? Thank

4 you.

5 BY MR. DAVIS:

6 Q. Doctor, you have what has been marked as

7 Exhibit 54 at your deposition. Would you look at

8 this document for a moment and tell me if you've

9 ever seen it before.

10 A. I saw this earlier today.

11 Q. Do you recall seeing this before today?

12 A. No, I don't.

13 Q. Did you ever receive an update

14 regarding -- strike that.

15 Did you ever see updates in this format

16 back in the 2001 time frame?

17 A. The format's unfamiliar to me.

18 Q. It is?

19 A. The format is unfamiliar to me.

20 Q. Do you recall receiving any updates

21 regarding 773 in, say, before March 13, 2001?

22 A. Yes. I periodically got information on

23 the status of the program.

24 Q. If you'd look at the beginning on Page 1

1 where it says, "Key issues facing ABT-773
2 development program are summarized before."

3 A. I see it.

4 Q. I'll just ask quickly. Were you aware
5 of the QTc issues that are referenced in this
6 document back in February of '01?

7 A. Let me read it, see what it says.

8 Yes. As characterized here, I was aware
9 of general issues with respect to QTc for drug
10 development programs in general as well as macrolide
11 antibiotics.

12 Q. Under the section that begins on the
13 next page titled Liver Toxicity Issues, were you
14 aware of those issues back in February of '01 as
15 they pertained to 773?

16 MR. PHILLIPS: Can you read back the question,
17 please.

18 (WHEREUPON, the record was read by the
19 reporter as requested.)

20 MR. PHILLIPS: I'll object that it's -- object
21 to the form.

22 BY THE WITNESS:

23 A. Generally speaking I was aware that the
24 FDA was concerned about hepatotoxicity. They're

1 concerned about all kinds of safety issues. I think
2 hepatotoxicity has always been one that people have
3 tried to come to terms with because it is so hard to
4 quantitate and understand because it is so common.

5 BY MR. DAVIS:

6 Q. The last paragraph in this section
7 titled Liver Toxicity Issues referencing the
8 Japanese bridging study, do you see that?

9 A. I do.

10 Q. That's the study you referred to earlier
11 today?

12 A. It is.

13 Q. You were aware of the results of that
14 study back in February of '01?

15 A. I was informed of them.

16 Q. How about the next section, the one
17 titled Phase III Tablet Program, were you aware of
18 the information that is described in that section
19 back in February of '01?

20 MR. PHILLIPS: Object to the form.

21 BY THE WITNESS:

22 A. I'll read it here.

23 I'm generally aware of this.

24 BY MR. DAVIS:

1 Q. How about the next section entitled
2 ABT-773 IV Formulation Program, were you generally
3 aware of the information contained in that section
4 back in February of '01?

5 MR. PHILLIPS: Object to the form.

6 BY THE WITNESS:

7 A. I think some of the characterizations
8 are inaccurate. I knew that we were not working --
9 well, I think we had -- I thought the focus of the
10 program was an oral formulation of ABT-773.

11 BY MR. DAVIS:

12 Q. And I'm sorry. You said the focus of
13 the program was an oral formulation, meaning the
14 focus was not an IV formulation?

15 A. That's correct.

16 Q. Is it true that as of February of '01
17 that Abbott's IV formulation program for ABT-773 was
18 unfunded?

19 MR. PHILLIPS: Objection, vague.

20 BY THE WITNESS:

21 A. I don't remember. I know work had taken
22 place. I don't remember what was going on precisely
23 at that time.

24 BY MR. DAVIS:

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1 Q. As you sit here today do you have any
2 information that leads you to believe that the
3 statement that the IV formulation program is
4 presently unfunded was untrue as of February of '01?

5 MR. PHILLIPS: Objection, lack of foundation.

6 BY THE WITNESS:

7 A. As I sit here today -- well, I don't
8 know who wrote this document. I don't know to whom
9 it was provided. I don't know if it was written by
10 a commercial person or an R&D person. I can't prove
11 or disprove the veracity of this sentence.

12 BY MR. DAVIS:

13 Q. And there is -- the next section
14 titled -- going back, I'm sorry, to the section
15 about IV formulation program.

16 You said that you think that some of the
17 characterizations in that section are inaccurate.
18 Which ones do you think are inaccurate?

19 A. Well, partial funding, I don't know what
20 that means.

21 Q. Where, I'm sorry?

22 A. I'm sorry. In the second paragraph,
23 "The ABT-773 IV program received partial funding," I
24 don't understand what that means. I mean, we fund

1 experiments through their completion one way or the
2 other, so I don't know what that's speaking to or
3 about.

4 "The IV program is important to overall
5 program because of the following." My recollection
6 was that this was first and foremost an oral
7 formulation, that was where almost all the value of
8 the product lay. And my recollection is that a lot
9 of people didn't want to do an IV formulation
10 because they thought it was a distraction and might
11 actually lead to its being niched in a subset of
12 patients that would undermine its overall value.

13 Q. Do you recall who any of those -- who
14 those people were?

15 A. These were general discussions that took
16 place with some of the commercial people. I don't
17 remember.

18 Q. Is there any other information that you
19 see in here that you can identify that you were not
20 aware of regarding the IV formulation program as of
21 February of '01?

22 MR. PHILLIPS: Object to the form, lack of
23 foundation.

24 BY THE WITNESS:

1 A. I can't speak to the accuracy of these
2 numbers for funding or what HPD -- HPD is the
3 Hospital Products Division, which is another
4 independent division of Abbott. They had some
5 interest that was peripheral to the program. I
6 can't speak on behalf of what they wanted or were
7 doing or funded.

8 BY MR. DAVIS:

9 Q. Were you generally aware of the funding
10 levels for ABT-773 programs back in February of '01?

11 MR. PHILLIPS: Objection, vague.

12 BY THE WITNESS:

13 A. I was generally aware, yes. I wasn't
14 accountable for the HPD funding or decisions.
15 Again, it was an independent division of Abbott
16 Laboratories and they would choose at times to buy
17 parts of programs or fund them for their own
18 purposes. But that was at their discretion; I
19 wasn't part of that decision process.

20 BY MR. DAVIS:

21 Q. There is a section here titled Pediatric
22 Program as well. Would you take a moment and read
23 that and tell me whether you were generally aware of
24 the information contained in that section as of

1 February of '01?

2 MR. PHILLIPS: Object to the form and lacks

3 foundation.

4 BY THE WITNESS:

5 A. I've read it. I'm sorry, I forget the

6 question.

7 BY MR. DAVIS:

8 Q. The question is were you generally aware

9 of the information described in that section

10 concerning pediatric program as of February of '01?

11 MR. PHILLIPS: Same objections.

12 BY THE WITNESS:

13 A. Generally aware. This sounds reasonably

14 accurate.

15 MR. DAVIS: Would you mark this, please, as

16 the next exhibit. I think we're up to Exhibit 55.

17 (WHEREUPON, a certain document was

18 marked Leonard Deposition Exhibit

19 No. 55, for identification, as of

20 06-01-2007.)

21 BY MR. DAVIS:

22 Q. Dr. Leonard, you have what's been marked

23 as Exhibit 55. Would you look at this document for

24 a moment and tell me if you recall seeing this

1 document before.

2 A. I don't remember this specific document.

3 Q. Do you recall seeing documents in this

4 format back in the early 2001 time frame?

5 A. I do.

6 Q. Do you recall seeing documents in this

7 format concerning ABT-773 in that time frame?

8 A. I do.

9 Q. Is it fair to say that you received

10 documents in this format for each of the compounds

11 for which you had supervisory responsibility back in

12 that time frame?

13 A. I don't believe that's the case, but for

14 most of them.

15 Q. Did you receive documents like this for

16 594?

17 A. I believe I did.

18 Q. And 518?

19 A. I don't remember.

20 Q. Who within Abbott prepared these

21 documents?

22 MR. PHILLIPS: Objection.

23 BY MR. DAVIS:

24 Q. And let me be specific to Exhibit 55.

1 Who within Abbott or what area within Abbott had
2 responsibility for preparing documents such as
3 Exhibit 55?

4 A. Yeah. These documents typically
5 originated with project teams. We did not have a
6 policy or formal part of some job description that
7 some particular member of the project team was
8 responsible for carrying it out, so I can't tell the
9 specific individual that prepared this. It may have
10 been a group effort for all I know.

11 Q. And when you received these -- by the
12 way, what did you call documents such as Exhibit 55?

13 A. This looks like what I would call a
14 monthly project status report.

15 Q. Did you review the monthly project
16 status reports for the compounds for which you had
17 supervisory responsibility back in the early 2001
18 time frame?

19 A. Some of them.

20 Q. Would you review them for 773?

21 A. On occasion.

22 Q. Did you try to keep up-to-date on the
23 status of the -- the development status of 773 back
24 in the early 2001 time frame?

1 A. I did. There are numerous means to do
2 that besides this.

3 Q. Would you take a look for a moment at
4 the third page of Exhibit 55. There is a --
5 underneath Key Project Issues and Risks one of the
6 risks or issues the last one is "150 milligrams QD
7 versus BID dose decision in CAP/sinusitis." Do you
8 see that?

9 A. I do.

10 Q. And if you look under potential or known
11 impact, would you read that box to yourself and then
12 tell me, please, when you're done.

13 A. I see it.

14 Q. First, who is the A -- is it AI? It
15 says "Current AI opinion is that QD may receive
16 regulatory challenge for approval in CAP unless data
17 is very compelling given PK profile of
18 150 milligrams QD." Who is the AI referred to
19 there, if you know?

20 A. Sure. AI stands for Abbott
21 International, which was the ex-US commercial arm of
22 the pharmaceutical products group.

23 Q. The same section goes on to state,
24 "However, BID dosing, while relatively minor

1 product, which were -- you know, they're here in
2 this document, primary respiratory tract infections
3 in adults. The IV formulation was very much an
4 add-on, and an elective one at that.

5 In fact, there was some discussion about
6 how important the IV formulation actually was. When
7 one explores intravenous forms and does that
8 primarily it's possibly to have your product niched
9 into the hospital patient population, which would
10 undermine the ultimate commercial success of the
11 product.

12 MR. DAVIS: Would you mark this, please, as
13 the next exhibit. We're up to 57.

14 (WHEREUPON, a certain document was
15 marked Leonard Deposition Exhibit
16 No. 57, for identification, as of
17 06-01-2007.)

18 BY MR. DAVIS:

19 Q. Dr. Leonard, you have what's been marked
20 as Exhibit 57?

21 A. I do.

22 Q. Would you look at this document for a
23 moment and tell me if you've ever seen it before.

24 MR. PHILLIPS: Well, let me point out,

- 1 Counsel, this document appears to bear a number
- 2 which I believe is -- is that a McKinsey?
- 3 MR. DAVIS: It's a McKinsey number, correct.
- 4 MR. PHILLIPS: Well, I'll just note that for
- 5 the record.
- 6 MR. DAVIS: That's fine.
- 7 BY THE WITNESS:
- 8 A. I don't remember this particular
- 9 document.
- 10 BY MR. DAVIS:
- 11 Q. Do you recall that Abbott retained
- 12 McKinsey & Company to provide consulting services
- 13 and assistance with the integration of the Knoll
- 14 acquisition?
- 15 A. We did.
- 16 Q. Did you work with people from McKinsey
- 17 for that purpose?
- 18 A. There were a couple of McKinsey people
- 19 who assisted on the R&D side of that integration,
- 20 yes.
- 21 Q. Was Mike Williams one of them?
- 22 A. Mike Williams was one of them, yes.
- 23 Q. And do you recall a Jessica Hopfield?
- 24 A. I do.

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1 Q. They both worked on that project?

2 A. They did. I don't think Jessica was

3 limited to the R&D part of it. If memory serves me

4 correctly, Mike I believe was.

5 Q. Approximately how many McKinsey people

6 worked on the project, as best you recall?

7 A. I can't answer that because there were a

8 series of subteams. For example, we had a clinical

9 subteam, a chemistry and manufacturing control

10 subteam, I believe there was a quality assurance

11 subteam. Without going back and looking at other

12 records, I can't tell you how many individual

13 subteams. They all had McKinsey people, so there

14 were several McKinsey folks involved.

15 Q. Who were the McKinsey people with whom

16 you had the most contact?

17 A. Most of my contact was with Mike

18 Williams and Jessica.

19 Q. Were they in charge of the project from

20 McKinsey's perspective, if you know?

21 MR. PHILLIPS: Lack of foundation.

22 BY THE WITNESS:

23 A. In charge. I don't know what that

24 means. There was -- they had supervision and I

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1 Q. Do you know who within Abbott had that
2 responsibility?

3 A. I can only speculate. I don't know.

4 Q. Typically -- based on your experience
5 typically who within Abbott or what organization
6 within Abbott would be responsible for entering into
7 or negotiating such an agreement?

8 A. I would expect Dr. Leiden, but I don't
9 know that that in fact happened.

10 Q. Who had the first idea or who initiated
11 the idea of retaining McKinsey to assist with the
12 integration?

13 A. I don't know.

14 MR. PHILLIPS: Objection to the form.

15 BY MR. DAVIS:

16 Q. Did people from McKinsey -- strike that.

17 It's fair to say the people from
18 McKinsey helped prepare materials that were used in
19 the course of meetings that were conducted during
20 the integration process; is that right?

21 A. That's correct.

22 MR. PHILLIPS: Objection, vague.

23 BY THE WITNESS:

24 A. It is correct that the McKinsey people

1 generated many documents during the course of the
2 integration process.

3 BY MR. DAVIS:

4 Q. And McKinsey people sat in on meetings
5 that occurred at Abbott during the course of the
6 integration process?

7 A. McKinsey people sat in on many of the
8 meetings but not all of them.

9 Q. Is it also fair to say that on occasion
10 McKinsey people were responsible for keeping track
11 of what occurred in the course of the Abbott
12 meetings?

13 MR. PHILLIPS: Object to the form.

14 BY THE WITNESS:

15 A. The McKinsey people generated documents
16 sometimes at our request, sometimes not at our
17 request, and I can't tell you how they decided what
18 to generate or for whom they were generating them.

19 BY MR. DAVIS:

20 Q. Do you recall on any occasions that
21 McKinsey people were charged with responsibility for
22 memorializing or keeping records of decisions made
23 or discussions that occurred at various Abbott
24 integration meetings?

1 MR. PHILLIPS: Object to the form.

2 BY THE WITNESS:

3 A. I recall meetings particularly of
4 subteams where as we would work out a -- like a CMC,
5 chemistry and manufacturing control strategy, or a
6 clinical strategy that for those subteams they would
7 collect the output of those teams.

8 BY MR. DAVIS:

9 Q. Do you recall that McKinsey people also
10 collected output from other types of meetings as
11 well?

12 A. Sometimes.

13 Q. Do you recognize Exhibit 57 as a
14 document that was prepared by McKinsey people for
15 purposes of the development portfolio review
16 kickoff, March 7, 2001?

17 A. I don't remember the specific document.

18 Q. Do you recall McKinsey preparing a
19 document for use at that kickoff?

20 A. I don't.

21 Q. Would you turn to the second page of
22 this document. There is a section titled Structure
23 of Presentation and it has your name along with
24 Dr. Leiden's name. Do you see that?

1 A. I do.

2 Q. Does this document accurately reflect
3 sort of your and Dr. Leiden's involvement in the
4 initial kickoff meeting for the portfolio review in
5 early March 2001?

6 MR. PHILLIPS: Objection, lack of foundation.

7 BY THE WITNESS:

8 A. I don't have a recollection of how we
9 began. I know we had a meeting, I know we had an
10 agenda. I don't recall opening statements and
11 specific slides being shown.

12 BY MR. DAVIS:

13 Q. Do you recall making some sort of
14 opening statements yourself in the course of that
15 meeting?

16 A. I don't.

17 Q. Do you recall ever explaining to anyone
18 any ground rules for that meeting?

19 A. I don't.

20 Q. Would you look, please, at the page of
21 the document that's numbered five in the lower
22 right-hand corner. It's entitled Decision-Making
23 Approach Going Forward. Do you see that?

24 A. I do.

1 Q. Would you read that page to yourself,
2 please, and tell me when you're done.

3 A. I've read it.

4 Q. Does this page fairly and accurately
5 describe the decision making approach that Abbott
6 utilized in the course of the I think it was March 7
7 through 9, 2001, initial portfolio review?

8 MR. PHILLIPS: Objection; assumes facts not in
9 the record. Object to the form.

10 BY THE WITNESS:

11 A. I don't specifically remember doing
12 this. We had a final prioritization meeting that
13 took place two months after this in May, which as I
14 recall was the basis of making prioritization
15 judgments for the portfolio that we had.

16 BY MR. DAVIS:

17 Q. I'm focusing for the moment, though, on
18 this meeting in March. You recall there was a
19 meeting in early March 2001 where they did an
20 initial portfolio prioritization?

21 A. I did.

22 Q. You participated in this, did you not?

23 A. I did.

24 Q. Does this page fairly and accurately

1 describe the decision making approach that was used
2 in that March 2001 meeting?

3 A. No. Because as I recall what ultimately
4 happened was the meeting turned into a learning
5 process of what in fact we had because this is the
6 first time we saw all of the projects, and we
7 decided that ultimately we would need a final
8 prioritization meeting which was -- led to the
9 genesis of the May meeting.

10 Q. Well, in this slide, for example, under
11 "What," it says, "Classify products into three
12 groups." Do you see that?

13 A. I do.

14 Q. Is that -- did Abbott personnel in fact
15 classify developments, compounds that were under
16 development into one of these three groups in the
17 course of the March 2001 portfolio review?

18 A. I don't specifically remember.

19 Q. Then the next section titled "When," do
20 you see the second bullet point, it says all
21 other -- the first bullet point, actually, says,
22 "Initial list of projects in the third group will be
23 communicated within one to two weeks." Do you see
24 that?

1 Q. What other prioritizations were going --
2 projects were underway?

3 A. Our discovery work.

4 Q. Was that -- who was the head of that
5 prioritization project?

6 A. Dr. Leiden.

7 Q. Did you participate in that?

8 A. I did.

9 Q. Were there separate meetings for that?

10 A. Yes.

11 Q. Were there any -- were there discussions
12 about discovery projects at the final prioritization
13 meeting in May?

14 A. I don't recall.

15 Q. Do you know whether this -- the
16 prioritization meetings that occurred between
17 March 7 and 9 were focused on the development
18 projects or the discovery projects?

19 MR. PHILLIPS: Objection; assumes facts not in
20 the record.

21 BY THE WITNESS:

22 A. My recollection is this was primarily
23 development based.

24 BY MR. DAVIS:

1 Q. Is that -- if you take a look at the
2 agenda that begins on Page 7 of this document you'll
3 see the list of products or projects that are
4 identified on this agenda?

5 A. I see them.

6 Q. Is that consistent with your
7 understanding that the purpose of this particular
8 development portfolio review was for development
9 projects?

10 A. It looks correct.

11 Q. Do you recall receiving output from
12 McKinsey in the aftermath of the March 7, 2001 --
13 March 7 through 9, 2001, initial portfolio review?

14 A. I don't.

15 MR. DAVIS: Let's mark this, please, as the
16 next exhibit. 58.

17 (WHEREUPON, a certain document was
18 marked Leonard Deposition Exhibit
19 No. 58, for identification, as of
20 06-01-2007.)

21 BY MR. DAVIS:

22 Q. Dr. Leonard, you have what's been marked
23 as Exhibit 58. Please take a moment and look at the
24 document and tell me if you've ever seen it before.

1 A. This looks like a document I was shown
2 earlier today.

3 Q. Had you ever seen it before earlier
4 today?

5 A. No.

6 Q. You're sure of that?

7 A. I am.

8 Q. Do you recall seeing any sort of summary
9 of decisions or discussions that occurred in the
10 March 7 through 9, 2001, initial portfolio
11 prioritization review?

12 A. Could you repeat that.

13 Q. Sure. Do you recall ever seeing any
14 summary or memorialization of decisions or
15 discussions that occurred in the initial portfolio
16 prioritization review between March 7 and 9 of 2001?

17 A. No, I don't.

18 Q. Do you know whether anyone ever created
19 such documents?

20 A. This would appear to be such a document.
21 I don't know its genesis.

22 Q. Do you recall -- if you'd just take a
23 look at the first page of the document, there are
24 references to various projects on the left-hand

1 Q. You recall some sort of presentation
2 that included safety issues?

3 A. All of our presentations tend -- when we
4 talk about a compound, efficacy always comes with
5 safety. You can't talk about them independent of
6 each other. Again, it's a benefit risk tradeoff.
7 And I think what this speaks to is the difficulty of
8 demonstrating the benefit risk profile that we hoped
9 to achieve with the compound given the information
10 that had emerged from the Ketek advisory committee
11 meeting.

12 Q. Do you recall the presentation or
13 reviewing the presentation that's referenced in
14 Exhibit 63?

15 A. Not specifically, no.

16 MR. DAVIS: Why don't we mark this as the next
17 exhibit, please.

18 (WHEREUPON, a certain document was
19 marked Leonard Deposition Exhibit
20 No. 64, for identification, as of
21 06-01-2007.)

22 BY MR. DAVIS:

23 Q. Dr. Leonard, you have what's been marked
24 as Exhibit 64. Look at this document for a moment

1 and tell me if you recall seeing this before.

2 A. I saw this earlier today.

3 Q. The very top e-mail in this document,

4 the first one that appears on Page 1 of the

5 document, appears to be an e-mail from Dr. Verlinden

6 to Dr. Sun, Dr. Bukofzer, and others, with a cc to

7 you. Do you see that?

8 A. I do.

9 Q. And the e-mail is dated from March

10 of 2001. Do you recall receiving this e-mail from

11 Dr. Verlinden?

12 A. I don't.

13 Q. It's -- the e-mail concerns ABT-773, you

14 agree?

15 A. I agree.

16 Q. In the first bullet it says -- the

17 e-mail says that, "For what they are worth, here are

18 summary thoughts on the way forward with 773 QT

19 issue." The first bullet point says, "Despite

20 significant issues with the quality of the QT data

21 collection to date, a QT signal has emerged from

22 both the preclinical and clinical programs."

23 What does that mean?

24 MR. PHILLIPS: Objection, lack of foundation.

1 BY THE WITNESS:

2 A. I can't speculate as to what

3 Dr. Verlinden specifically meant when she wrote this

4 document.

5 BY MR. DAVIS:

6 Q. Well, when you received this e-mail did

7 you understand that to mean that she thought that

8 there was indication in the data that had been

9 collected to date that there might be QT problems or

10 issues associated with 773?

11 A. I don't remember even specifically

12 reading this e-mail. Dr. Verlinden at that time was

13 involved with an effort at the company to try to

14 create a QT evaluation process so that out of the

15 absence of standards that existed for the FDA at

16 that time we could have our own standards so that we

17 could say that all of our programs were subjected

18 to.

19 This work at this time was done, as far

20 as I know, the same way it was done with all

21 programs at Abbott, and all programs in other

22 companies at that time, which was to collect large

23 amounts of clinical data and look for signals in the

24 clinical data. To the best of my recollection we

1 didn't have a QT signal in patients, which is the
2 ultimate sine qua non.

3 The quality of QT data collected -- you
4 know, the only thing that was under debate at that
5 time was what would be the proper, most stringent
6 way of collecting QT data if one did it beyond the
7 ways that the industry was doing it at that time,
8 and she certainly had some thoughts about that.
9 She'd interacted with outside experts, she worked to
10 prepare the QT evaluation process and standard that
11 we ultimately went to.

12 Q. Did you ever have any discussions with
13 Dr. Verlinden as to what she meant when she said
14 that a QT signal has emerged from both the
15 preclinical and clinical programs?

16 A. No.

17 Q. Is Dr. Verlinden a capable researcher
18 and physician?

19 A. She's not a physician. She's an
20 analytical chemist who has worked in clinical
21 development.

22 Q. Did you think she was capable when she
23 worked at Abbott?

24 A. I did.

1 MR. PHILLIPS: Objection, vague.

2 MR. DAVIS: Let's mark this as the next

3 exhibit, please.

4 (WHEREUPON, a certain document was

5 marked Leonard Deposition Exhibit

6 No. 65, for identification, as of

7 06-01-2007.)

8 BY MR. DAVIS:

9 Q. Dr. Leonard, you have what's been marked

10 as Exhibit 65 at your deposition. Would you look at

11 this document for a moment and tell me if you recall

12 ever seeing it before.

13 A. I don't remember seeing this particular

14 document.

15 Q. Did McKinsey provide assistance to

16 Abbott in terms of resource allocation in the course

17 of the Knoll integration project?

18 A. I don't understand the question. Do you

19 mean make recommendations?

20 Q. Yes. Any sort of consulting assistance

21 regarding resource allocation?

22 A. What I saw was a series of subteams that

23 worked usually with support from the McKinsey

24 people. As teams went and looked at their work, we

1 made recommendations as to what we would continue,
2 primarily from a site point of view, head count
3 reductions, as we were integrating the two
4 companies. My recollection is that McKinsey didn't
5 tell us what to do. They in these subteams would
6 help to facilitate discussions and capture what was
7 stated there.

8 Q. So it would be fair to say that McKinsey
9 did provide assistance? They didn't necessarily
10 instruct you what to do, but they did provide a
11 consulting assistance regarding resource allocation?

12 A. Yeah.

13 MR. PHILLIPS: Objection, vague.

14 BY THE WITNESS:

15 A. They assisted. They did work that we
16 didn't have to do.

17 BY MR. DAVIS:

18 Q. Now, earlier today we talked about that
19 final prioritization preview that Abbott undertook
20 in May 2001. Did McKinsey assist in that process?

21 A. McKinsey was there, yes.

22 Q. Was that review, that early May review,
23 held offsite?

24 A. I believe it was, yes.

1 Q. Do you recall where?

2 A. I think the May meeting was held in Lake
3 Bluff, Illinois. There was a place, it doesn't
4 exist anymore, called the Harrison House which was
5 an offsite facility where we could go for large
6 meetings. I think that's where we did it.

7 Q. Who from McKinsey was there, as best you
8 recall?

9 A. The one person I do remember was Jessica
10 Hopfield because I remember she made a presentation
11 about the pharmaceutical industry as a whole.

12 Q. At that May meeting?

13 A. That's my recollection.

14 Q. How long did the May meeting last?

15 A. I know it was two days. It may have
16 been three. I know it was at least two days, I
17 guess I should say.

18 Q. Do you recall what days of the week the
19 meeting took place?

20 A. I don't. I'd have to look at my
21 calendar.

22 Q. Do you recall whether it was a Friday
23 and Saturday?

24 A. I don't remember.

1 is a reference there to Biaxin?

2 A. Yes.

3 Q. Is that an Abbott compound?

4 A. It is.

5 Q. Is that an antibiotic?

6 A. It is.

7 Q. Are antibiotics one of Abbott's

8 traditional strengths?

9 A. They are.

10 Q. Was 773 an antibiotic?

11 A. Absolutely.

12 Q. If you'd look for a moment at also --

13 excuse me, just for a moment.

14 I'm wrong. I apologize. One moment,

15 please.

16 MR. PHILLIPS: No problem.

17 BY MR. DAVIS:

18 Q. Actually, would you look at the page

19 that ends in 7348.

20 A. Okay.

21 Q. There is a page there titled "2003

22 Pipeline"?

23 A. I see it.

24 Q. One of the compounds listed there under

1 Q. Under Phase I there is a reference to

2 ABTT-894. Do you see that?

3 A. I do.

4 Q. It says pain underneath?

5 A. Yes.

6 Q. Is that the indication for which Abbott

7 was pursuing ABT-59 -- 894 back in 2003?

8 A. That's correct.

9 Q. And 894 is another NNR; is that right?

10 A. It is.

11 MR. DAVIS: Let's mark this as the next

12 exhibit, please.

13 (WHEREUPON, a certain document was

14 marked Leonard Deposition Exhibit

15 No. 73, for identification, as of

16 06-01-2007.)

17 BY MR. DAVIS:

18 Q. Dr. Leonard, you have what's been marked

19 as Exhibit 73. Would you look at the document for a

20 moment and just tell me, please, if you've seen it

21 before.

22 A. Okay.

23 Q. Have you seen it before?

24 A. I don't -- I don't know. I don't

1 remember, I guess.

2 Q. In the -- and it's titled PPG R&D

3 Review?

4 A. Right.

5 Q. What's PPG?

6 A. Pharmaceutical Products Group.

7 Q. Have you participated in any PPG R&D

8 reviews in the year 2006?

9 A. I have but not all of them.

10 Q. If you look in the third page of this

11 document. And I apologize, the one that is

12 numbered 2.

13 A. Right.

14 Q. Do you see in the lower left-hand corner

15 there is a notation, "MDW PPG R&D Review:

16 meeting 1"?

17 A. Right.

18 Q. MDW, that's Miles White's initials,

19 right?

20 A. They are.

21 Q. Do you recall participating in any sort

22 of PPG R&D review with Mr. White back in March

23 of 2006?

24 A. Yes, I do.

1 Q. And do you recognize these slides as
2 being from that review?

3 A. I recognize some of them. I don't
4 remember others.

5 Q. Is it fair to say that information that
6 would be provided by Abbott personnel to Mr. White
7 in the course of an R&D review would be realistic
8 and accurate and truthful to the best of the ability
9 of the people within Abbott?

10 A. Of course.

11 MR. DAVIS: Let's mark this, please, as the
12 next exhibit.

13 BY THE WITNESS:

14 A. I would just add I didn't have my
15 current job at the time that this was created.

16 BY MR. DAVIS:

17 Q. I'm sorry?

18 A. I was adding that I didn't have my
19 current job when this document was created.

20 Q. What position did you hold at that time?

21 A. I was vice president global medical
22 scientific affairs. I was promoted to head of R&D
23 in April, which is after this.

24 Q. But as best you recall you did in fact

1 attend the March 2006 meeting with Mr. White?

2 A. I don't -- well, March 23. I don't

3 remember. I went to one with him; I didn't go to

4 all of them.

5 Q. We're up to --

6 MR. WITTY: 74.

7 MR. DAVIS: 74.

8 (WHEREUPON, discussion was had off the

9 record.)

10 (WHEREUPON, a certain document was

11 marked Leonard Deposition Exhibit

12 No. 74, for identification, as of

13 06-01-2007.)

14 BY MR. DAVIS:

15 Q. Dr. Leonard, you have what's been marked

16 as Exhibit 74. Would you look at that document for

17 me for a moment and tell me if you've seen that one

18 before?

19 A. I sue.

20 Q. What is this? What is Exhibit 74?

21 A. After Dr. Leiden left the company some

22 of us -- well, Rick Gonzalez, corresponding to RAG,

23 assumed responsibility for the pharmaceutical

24 products group, which was the group that Dr. Leiden

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VIA FEDERAL EXPRESS

Joseph H. Zwicker, Esq.
Choate Hall & Stewart LLP
Two International Place
Boston, MA 02110

Re: *John Hancock Life Ins. Co., et al. v. Abbott Laboratories*

Dear Joe:

Enclosed please find the executed errata sheet and signature page for the deposition transcript of Dr. John Leonard.

If you have any questions or comments, please give me a call.

Sincerely,


Gregory D. Phillips

Enclosures
3225223.1

JOHN M. LEONARD, M.D., JUNE 1, 2007
HIGHLY CONFIDENTIAL

205044

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JOHN HANCOCK LIFE INSURANCE)
COMPANY, JOHN HANCOCK VARIABLE)
LIFE INSURANCE COMPANY AND)
MANULIFE INSURANCE COMPANY)
(f/k/a INVESTORS PARTNER)
INSURANCE COMPANY),)
Plaintiffs,)

-vs-

ABBOTT LABORATORIES,
Defendant.)

) No. 05-11150-DPW

I hereby certify that I have read the
foregoing transcript of my deposition given at the
time and place aforesaid, consisting of Pages 1 to
534, inclusive, and I do again subscribe and make
oath that the same is a true, correct and complete
transcript of my deposition so given as aforesaid,
and includes changes, if any, so made by me.

JOHN M. LEONARD, M.D.

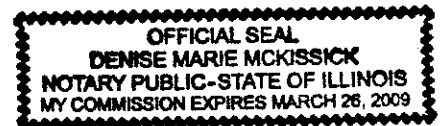
SUBSCRIBED AND SWORN TO DENISE M. MCKISSICK

before me this 5TH day July

of July, A.D. 2007.

Notary Public

COUNTY OF LAKE, ILLINOIS



Denise M. McKissick

Errata Sheet

Page: 1 Of Total Pages: 1

I wish to make the following changes to my deposition/statement:

Page #: 351, Line #: 2

As appears in Transcript: I think 64 is meant to be 46

To: _____

Reason: _____

Page #: 373, Line #: 2

As appears in Transcript: Yes, it.

To: Yes, it is.

Reason: I think that is what I said

Page #: 397, Line #: 19

As appears in Transcript: doesn't mean he makes mistakes

To: doesn't mean he does not make mistakes

Reason: I believe this is what I said

Page #: 532, Line #: 8

As appears in Transcript: that?

To: that.

Reason: It was not a question.

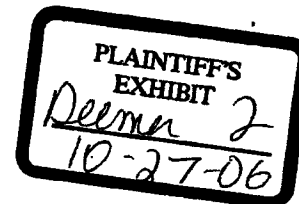
20 Jul 2007
DATE

[Signature]
DEPONENT'S SIGNATURE

Leonard Deposition Exhibit 1

P's Exhibit 32

Part 1



RESEARCH FUNDING AGREEMENT

by and between

ABBOTT LABORATORIES

and

JOHN HANCOCK LIFE INSURANCE COMPANY,

JOHN HANCOCK VARIABLE LIFE INSURANCE COMPANY,

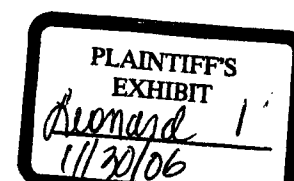
and

INVESTORS PARTNER LIFE INSURANCE COMPANY

dated as of

March 13, 2001

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6.	Miscellaneous Choate, Hall & Stewart memoranda to John Hancock regarding "outstanding issues"
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RESEARCH FUNDING AGREEMENT

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and

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dated as of

March 13, 2001

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RESEARCH FUNDING AGREEMENT

This Research Funding Agreement is made as of March 13, 2001, by and between Abbott Laboratories; an Illinois corporation ("Abbott"), with its principal offices at 100 Abbott Park Road, Abbott Park, Illinois 60064-6049, and John Hancock Life Insurance Company, a Massachusetts corporation, John Hancock Variable Life Insurance Company, a Massachusetts corporation, and Investors Partner Life Insurance Company, a Delaware corporation (collectively, "John Hancock"), each with its principal offices at 200 Clarendon Street, Boston, Massachusetts 02117.

WITNESSETH

WHEREAS, Abbott is a global healthcare company actively engaged in the research and development of human pharmaceutical products;

WHEREAS, Abbott is interested in obtaining additional funding to support such research and development activities with respect to certain pharmaceutical products which are under development; and

WHEREAS, John Hancock is interested in providing such additional funding in exchange for the right to receive future milestone and royalty payments from Abbott.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and undertakings contained herein, the parties hereto agree as follows:

ARTICLE I
DEFINITIONS

In addition to the other terms defined elsewhere herein, the following terms shall have the following meanings when used in this Agreement (and any term defined in the singular shall have the same meaning when used in the plural and vice versa, unless stated otherwise):

1.1 "Affiliate" shall mean, with respect to each party, any corporation or other form of business organization, which directly or indirectly owns, controls, is controlled by, or is under common control with, such party. An entity shall be regarded as being in control of another entity if the former entity has the direct or indirect power to order or cause the direction of the policies of the other entity whether (i) through the ownership of more than fifty percent (50%) in the United States, or thirty percent (30%) or more outside the United States, of the outstanding voting securities (or other ownership interest for a business organization other than a corporation) of that entity; or (ii) by contract, statute, regulation or otherwise.

1.2 "Aggregate Carryover Amount" shall have the meaning given in Section 3.3.

-2-

1.3 "Aggregate Spending Target" shall mean Six Hundred Fourteen Million Dollars (\$614,000,000).

1.4 "Annual Carryover Amount" shall have the meaning given in Section 3.3.

1.5 "Annual Minimum Spending Target" for each Program Year, shall mean the sum of (i) the Program Payment of John Hancock for such Program Year as specified in Section 3.1, (ii) Fifty Million Dollars (\$50,000,000), and (iii) any Annual Carryover Amount for the prior Program Year pursuant to Section 3.3. With respect to the fifth Program Year, the "Annual Minimum Spending Target" shall mean the Annual Carryover Amount for the prior Program Year pursuant to Section 3.3.

1.6 "Annual Research Plan" shall mean, for the Program Years in the Program Term, a reasonably and consistently detailed statement of the objectives, activities, timetable and budget for the Research Program for every Program Year remaining in the Program Term, it being understood that less detail shall be required for Program Years that are not the current Program Year. The first Annual Research Plan is attached as Exhibit 1.6. "Annual Research Plan" shall mean, for those years occurring after the expiration of the Program Term, a reasonably and consistently detailed statement of the objectives, activities, timetable and budget for the Research Program for such year only.

1.7 "Bundled Product" shall have the meaning given in paragraph (b) of the definition of Net Sales.

1.8 "Ceased Program" shall mean at least one year has elapsed since Abbott ceased its directed efforts with respect to the applicable Preclinical Program (FTI Program, ED Program or MMPI Program), meaning that Abbott has eliminated the funding for the established research program identified by a core group of researchers dedicated to the applicable Preclinical Program. The continued existence of a researcher separate and apart from such core group shall not affect the determination that a Preclinical Program has ceased.

1.9 "Combination Product" shall mean any product containing one or more Program Compounds combined as a single pharmaceutical product with one or more other therapeutically active ingredients.

1.10 "Commercially Reasonable Efforts" shall mean efforts which are consistent with those normally used by other pharmaceutical companies with respect to other pharmaceutical compounds or products which are of comparable potential commercial value and market potential at a similar stage of development or product life, taking into account, without limitation, issues of safety and efficacy, compound or product profile, proprietary status, the regulatory environment and the status of the compound or product and other relevant scientific factors.

1.11 "Compound Reports" shall have the meaning given in Section 12.2(i).

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1.12 "Confidential Information" shall have the meaning given in Section 10.2.

1.13 "Delivery System Product" shall have the meaning given in paragraph (d) of the definition of Net Sales.

1.14 "Dollars" or "\$" shall mean United States dollars.

1.15 "ED Program" shall mean all of Abbott's discovery efforts to identify compounds (including the identification of pre-clinical and development compounds owned by third parties) which modulate dopamine receptors for the purpose of treating erectile dysfunction.

1.16 "Eisai Agreement" shall mean the License Agreement dated June 29, 2000 between Eisai Co., Ltd. and Abbott related to the Program Compound known as ABT-751.

1.17 "Eisai Territory" shall mean the countries listed on Exhibit 1.17 hereto.

1.18 "Execution Date" shall mean the date set forth in the introductory paragraph to this Agreement.

1.19 [Intentionally Omitted.]

1.20 "FDA" shall mean the U.S. Food and Drug Administration or any successor entity thereto.

1.21 "First Commercial Sale" shall mean the first sale of a Product in a given country by Abbott, its Affiliates or Licensees to an unaffiliated third person after Regulatory Approval has been granted in such country.

1.22 "FTI Program" shall mean all of Abbott's discovery efforts to identify compounds (including the identification of pre-clinical and development compounds owned by third parties) which act as farnesyl transferase inhibitors for the purpose of treating cancer.

1.23 "In-License Agreements" shall mean the Eisai Agreement, the Wakunaga Agreement and the Taisho Agreement.

1.24 "International Territory" shall mean all areas of the world outside the U.S. Territory.

1.25 "Investigational New Drug Application" shall mean an investigational new drug application filed with the FDA in order to commence human clinical testing of a drug in the United States.

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1.26 "Licensee" shall mean any party licensed or otherwise authorized in writing by Abbott, its Affiliates or its licensees to market, distribute or sell Products and from whom Abbott receives a royalty or other payment based upon sales of Products by such party, its affiliates or its licensees (it being understood that a party that is a merely a distributor, wholesaler or similar reseller of Products is not a Licensee hereunder). In no case shall Eisai Co., Ltd. or Taisho Pharmaceutical Co., Ltd. be considered Licensees under the terms of the Eisai Agreement or Taisho Co-Development Agreement with respect to the Eisai Territory or Japan, respectively.

1.27 "Losses" shall mean any claims, demands, liabilities, costs, damages, judgments, settlements and other reasonable expenses (including attorneys' fees).

1.28 "Milestone Payment" shall have the meaning given in Section 6.3.

1.29 "MMPI Program" shall mean all of Abbott's discovery efforts to identify compounds (including the identification of pre-clinical and development compounds owned by third parties) that inhibit matrix metalloproteinase and treat cancer.

1.30 "NDA" shall mean a New Drug Application (as defined by the FDA) filed with the FDA for the purpose of obtaining Regulatory Approval of a Product in the U.S. Territory.

1.31 "Net Sales" shall mean:

- (a) the total gross sales of the Products (or, for purposes of clauses (b) and (c), the Bundled Products and Combination Products), in each case as set forth on the invoices for such sales by Abbott, its Affiliates and Licensees to unaffiliated third parties in any given period, plus, if applicable, the fair market value of all properties and services received in consideration of a sale of the Products (or, for purposes of clauses (b) and (c), the Bundled Products and Combination Products) by Abbott, its Affiliates and Licensees to unaffiliated third parties during such period, less the following deductions directly paid or actually incurred by Abbott, its Affiliates or Licensees during such period with respect to the sale of the Products (or, for purposes of clauses (b) and (c), the Bundled Products and Combination Products) to the extent included in the gross invoiced sales price therefor:
 - (i) discounts, credits, rebates, allowances, adjustments, rejections, recalls and returns;
 - (ii) price reductions or rebates, retroactive or otherwise, imposed by government authorities;
 - (iii) sales, excise, turnover, inventory, value-added and similar taxes assessed on the royalty-bearing sale of Products;

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- (iv) transportation, importation, insurance and other handling expenses directly chargeable to the royalty-bearing sale of Products;
 - (v) charge backs granted to unaffiliated drug wholesalers; and
 - (vi) the portion of management fees paid to unaffiliated group purchasing organizations that relate specifically to the royalty-bearing sale of Products.
- (b) With respect to a Product which is sold together with any other products and/or services in a country at a unit price, whether packaged together or separately (a "Bundled Product"), the Net Sales of such Bundled Product shall first be calculated in accordance with the definition of Net Sales under paragraph (a), and then the Net Sales of such Bundled Product shall be determined on a country-by-country basis as follows:
- (i) multiply the Net Sales of such Bundled Product in such country by the fraction $A/(A+B)$ where A is the average selling price of such Product in such country when sold separately and B is the total of the average selling prices in such country of each such other product(s) and/or service(s) in such Bundled Product when sold separately; or
 - (ii) if (x) either the average selling price of such Product or the total of the average selling prices of each such other products and/or services in such Bundled Product in such country is not available as of such date or (y) such Product is not sold separately in such country, multiply the Net Sales of such Bundled Product in such country by a percentage determined by the mutual agreement of the Parties which represents the proportionate economic value in such country of such Product relative to the economic value in such country contributed by the other products and/or services in such Bundled Product.
- (c) With respect to a Combination Product, the Net Sales of such Combination Product shall first be calculated in accordance with the definition of Net Sales under paragraph (a), and then the Net Sales of such Combination Product shall be determined on a country-by-country basis as follows:
- (i) multiply the Net Sales of such Combination Product in such country by the fraction $A/(A+B)$, where A is the total of the average selling prices of the Program Compounds in such

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Combination Product when sold separately in such country and B is the total of the average selling prices of each other therapeutically active ingredient when sold alone as a pharmaceutical product in such country; or

- (ii) if (x) either the average selling price of all Program Compounds in such Combination Product or the total of the average selling prices of each other therapeutically active ingredient in such Combination Product in such country is not available or (y) such Program Compounds are not sold separately in such country, multiply the Net Sales of such Combination Product by a percentage determined by mutual agreement of the Parties, which represents the proportionate economic value in such country of all Program Compounds in such Combination Product relative to the economic value in such country contributed by all other therapeutically active ingredients in such Combination Product.
- (d) For purposes of this paragraph (d), a "Premium Delivery System" means any delivery system comprising device(s), equipment, instrumentation or other non-ingestible components (but not solely containers or packaging) designed to assist in the administration of a Product, such as the Abbott ADD-Vantage® System. With respect to a Product which is sold together with a Premium Delivery System (a "Delivery System Product") in a country at a unit price, the Net Sales of such Delivery System Product shall first be calculated in accordance with the definition of Net Sales under paragraph (a), and then the Net Sales of such Product shall be determined on a country-by-country basis as follows:
 - (i) if the Product is sold separately without the Premium Delivery System in a country, reduce the Net Sales of such Delivery System Product in such country by the amount that the average selling price of the Delivery System Product in such country exceeds the average selling price of such Product as sold separately in such country; or
 - (ii) if the Product is not sold separately without the Premium Delivery System in such country, reduce Net Sales of such Delivery System Product by an amount, determined by mutual agreement of the Parties, which represents the proportionate economic value in such country added by the Premium Delivery System.
- (e) Net Sales shall not include any sales of Products containing one Program Compound (and no other Program Compound) known as (i) ABT-751 by Eisai Co. Ltd., its affiliates or licensees in the Eisai Territory or (ii) ABT-

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773 by Taisho Pharmaceutical Co., Ltd., its affiliates or licensees in Japan. Notwithstanding the foregoing sentence, Net Sales shall include in all instances sales by such parties of such products that are outside such territories, respectively.

1.32 "Parties" shall mean Abbott and John Hancock.

1.33 "Patents" shall have the meaning set forth in Section 12.2(e).

1.34 "Phase I Clinical Trial" shall mean a clinical trial of a Program Compound which utilizes a limited number of human beings preliminarily to address safety and to determine what doses can be safely tolerated.

1.35 "Phase II Clinical Trial" shall mean a controlled clinical trial, the primary objective of which is to ascertain additional data regarding the safety and tolerance of one of the Program Compounds and preliminary data regarding such Program Compound's efficacy.

1.36 "Phase III Clinical Trial" shall mean one or a series of controlled pivotal studies of a specific Program Compound by administration of such Program Compound to human beings where the principal purpose of such trial is to provide confirmatory safety and efficacy data necessary to support the filing for Regulatory Approval of a Product.

1.37 "Preclinical Programs" shall mean the following preclinical and clinical programs with potential backup compounds in accordance with Section 4.3(a): the FTI Program, the ED Program and the MMPI Program.

1.38 "Premium Delivery System" shall have the meaning given in paragraph (d) of the definition of Net Sales.

1.39 "Product" shall mean any product containing one or more of the Program Compounds as an active ingredient, alone or in combination with other active ingredients (including any Bundled Product and any Combination Product).

1.40 "Program Compounds" shall mean (i) the compounds listed on Exhibit 1.40; (ii) the first compound (the selection of which shall be consistent with Abbott using Commercially Reasonable Efforts) from each of the Preclinical Programs to enter Phase I Clinical Trial; (iii) any compounds or products substituted or added by Section 4.3; (iv) all line extensions and formulations of the foregoing; and (v) all analogs, isomers, improvements, derivatives and modifications of the foregoing unless such analog, isomer, improvement, derivative or modification would be considered a new chemical entity and required by the FDA to reenter Phase I Clinical Trial. A compound or product shall be considered a Program Compound regardless of the indication for which it is used.

1.41 "Program Inventions" shall have the meaning given in Section 5.1.

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1.42 "Program Payments" shall have the meaning given in Section 3.1.

1.43 "Program Related Costs" shall mean (i) all direct and indirect costs and expenses that are incurred by Abbott on the Research Program during a given Program Year and allocated in a manner consistent with Abbott's internal, pharmaceutical products division-wide allocation procedures; and (ii) the milestone and license fees paid during a given Program Year or during any extension period of the Program Term by Abbott to (a) Eisai Co. Ltd. (not to exceed Eighteen Million Dollars (\$18,000,000) in the aggregate with respect to the Program Compound known as ABT-751 pursuant to the Eisai Agreement) and (b) Wakunaga Pharmaceutical Co., Ltd. (not to exceed Twenty Seven Million Five Hundred Thousand Dollars (\$27,500,000) in the aggregate with respect to the Program Compound known as ABT-492 pursuant to the Wakunaga Agreement). Any payments made by Abbott to John Hancock pursuant to Sections 6.2 and 6.3(a), (b), (c), (d) and (e) shall constitute Program Related Costs. Any payment made by Abbott to John Hancock pursuant to Section 6.3(f) shall not constitute Program Related Costs. Set forth on Exhibit 1.43 is an example of the calculation of Program Related Costs for a particular Program Compound.

1.44 "Program Term" shall mean a period of four (4) consecutive Program Years.

1.45 "Program Year" shall mean a period of twelve (12) consecutive calendar months commencing on January 1 of each year, except that the first Program Year shall commence on the Execution Date and end on December 31, 2001.

1.46 "Quarterly Reporting Period" shall mean the calendar quarter with respect to the U.S. Territory together with the fiscal quarter ending on the final day of February, May, August and November (as the case may be) with respect to the International Territory. For example, the Quarterly Reporting Period that comprises the second calendar quarter with respect to the U.S. Territory also includes the period from March 1 through May 31 with respect to the International Territory. If Abbott adopts the calendar year as its fiscal year for the International Territory, then the Quarterly Reporting Period for the International Territory shall also be the calendar quarter.

1.47 "Research Program" shall mean all of Abbott's, its Affiliates' and Subcontractors' activities directed towards obtaining Regulatory Approval for the Products, including research, development, safety and efficacy studies, clinical trials, process development, formulation work, regulatory, quality, data collection and analysis and project management.

1.48 "Regulatory Approval" shall mean: (i) with respect to the U.S. Territory, the receipt of approval from the FDA to market a Product in the U.S. Territory; and (ii) with respect to any country in the International Territory, receipt of the governmental approvals required to market a Product in such country, including any pricing and reimbursement authorization required in such country.

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1.49 "Replacement Compound" shall mean a compound (i) made available to Abbott as a result of any transaction involving Abbott or its Affiliates (whether by merger, acquisition or sale of assets or equity, or by license or otherwise), (ii) used for the same class of indications as the Ceased Compound (for example, anti-infectives, cancer, cardiovascular or pain), and (iii) having at least the current and projected potential commercial value to John Hancock as the Ceased Compound.

1.50 "Royalty Term" shall mean, with respect to each Product in each country, a period of ten (10) years from the later of (x) the date of First Commercial Sale of such Product in such country and (y) the two year anniversary of the Execution Date; provided that (i) the obligation to make royalty payments on the Product shall not begin until the two-year anniversary of the Execution Date (and only with respect to Net Sales occurring on or after such date) and (ii) Abbott's obligation to make royalty payments shall cease on December 31, 2015.

1.51 "Subcontractor" shall have the meaning given in Section 2.4.

1.52 "Taisho Agreement" shall mean the Co-Development Agreement dated September 30, 1997 between Taisho Pharmaceutical Co., Ltd. and Abbott related to the Program Compound known as ABT-773.

1.53 "Territory" shall mean both the U.S. Territory and the International Territory, excluding the Eisai Territory with respect to the Program Compound known as ABT-751.

1.54 "U.S. Territory" shall mean the United States of America, excluding Puerto Rico and the U.S. Virgin Islands.

1.55 "Wakunaga Agreement" shall mean the License Agreement dated December 1, 1999 between Wakunaga Pharmaceutical Co., Ltd. and Abbott related to the Program Compound known as ABT-492.

ARTICLE 2 ANNUAL RESEARCH PROGRAM

2.1 Research Program Term. The Research Program shall be conducted by Abbott during the Program Term, and beyond the Program Term until Abbott either abandons development in accordance with the terms hereof or receives Regulatory Approval for each Program Compound, or some combination thereof.

2.2 Research Plan. The Research Program shall be conducted by Abbott in each Program Year in accordance with the Annual Research Plan for such Program Year. The Annual Research Plan will be provided to John Hancock until Abbott either abandons development in accordance with the terms hereof, or receives Regulatory Approval for, each Program Compound in the U.S. Territory, or some combination thereof. The Annual Research Plan shall be prepared

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by Abbott and presented to John Hancock at least forty-five (45) days prior to the start of each Program Year. The first Annual Research Plan is attached as Exhibit 1.6. Abbott may modify the Annual Research Plan from time to time in order to best meet the objectives of the Research Program. Any such modifications to the Annual Research Plan shall be promptly provided to John Hancock. In addition, Abbott shall provide an Annual Research Plan for each year after the end of the Program Term as long as there is an active research program for any Program Compounds.

2.3 Conduct of Research. Abbott shall use Commercially Reasonable Efforts to conduct the Research Program in good scientific manner and using good laboratory practices, to achieve the objectives of the Research Program efficiently and expeditiously and to comply with all applicable laws and regulations. Notwithstanding anything in this Agreement to the contrary, Abbott does not represent, warrant or guarantee that the Research Program will be successful in whole or in part or result in the registration or commercialization of any pharmaceutical products or that any Products obtaining Regulatory Approval will be a commercial success.

2.4 Subcontracting Research. Abbott may subcontract or outsource to Affiliates or third persons (each, a "Subcontractor") any portion of the Annual Research Plan. Consistent with Abbott's past practices, each Subcontractor shall enter into a confidentiality agreement with Abbott and agreements pursuant to which such Subcontractor is required to comply with all applicable laws and regulations, including conducting the Research Program in good scientific manner and using good laboratory practices, with respect to its work on the Research Program. Abbott shall supervise and be responsible under this Agreement for the work of each such Subcontractor on the Research Program and no subcontracting or outsourcing shall relieve Abbott of any of its obligations hereunder.

2.5 Research Reports and Records. Abbott shall, no later than thirty (30) days before the last day of each Program Year, provide John Hancock with a reasonably detailed report setting forth the status of the Research Program and all Program Related Costs expended by Abbott during such Program Year. The Program Related Costs set forth in such report may include good faith estimates with respect to the last three (3) months of the Program Year, provided that the report under this Section 2.5 for the following Program Year contains the actual Program Related Costs for that three (3) month period. Such report shall also contain such other information related thereto as John Hancock may reasonably request from time to time. Abbott shall, and shall cause each Subcontractor to, maintain complete and accurate records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and for purposes of demonstrating compliance with the terms hereof, that fully and properly reflect all work done, results achieved and Program Related Costs expended in performance of the Research Program. The books and records of Abbott and each Subcontractor related to the Research Program, including, without limitation, those related to the expenditure of Program Related Costs, shall be subject to copying, inspection and audit by (and at the expense of) John Hancock at any time and from time to time. Such audit shall occur upon reasonable notice and during normal business hours by an independent auditor selected by John Hancock and reasonably acceptable to Abbott. John Hancock and its independent auditor shall maintain such

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records and information of Abbott in confidence in accordance with Article 10 and shall not use such records or information except to the extent permitted by this Agreement, including any enforcement of the provisions hereof. In the event that such audit reveals any material breach of Abbott's responsibilities hereunder, Abbott shall (i) pay the reasonable fees and expenses charged by such auditor, and (ii) fully and promptly cure such breach.

ARTICLE 3 RESEARCH FUNDING

3.1 John Hancock Program Payments. John Hancock shall make the following installment payments on the applicable payment date (the "Payment Date"), for the applicable Program Year, to Abbott to help support the Research Program (the "Program Payments"):

<u>Payment Date</u>	<u>Amount</u>	<u>Program Year</u>
December 1, 2001	\$50,000,000	First
December 1, 2002	\$54,000,000	Second
December 1, 2003	\$58,000,000	Third
December 1, 2004	\$52,000,000	Fourth

All Program Payments shall be expended by Abbott on Program Related Costs and for no other purpose. If John Hancock has not received at least thirty (30) days prior to the Payment Date both (i) the Annual Research Plan for such year and (ii) the report described in Section 2.5 for the previous Program Year, then John Hancock's obligation to make the Program Payment due on such Payment Date shall be suspended until thirty (30) days have elapsed from the date of John Hancock's receipt of both such Annual Research Plan and report.

3.2 Abbott Funding Obligation. Abbott shall spend on Program Related Costs: (i) during each Program Year, at least the Annual Minimum Spending Target for such Program Year and (ii) at least the Aggregate Spending Target during the Program Term. John Hancock's sole and exclusive remedies for Abbott's failure to fund the Research Program in accordance with this Section 3.2 (but not for any other breach of Abbott's other obligations hereunder) are set forth in Sections 3.3 and 3.4.

3.3 Carryover Provisions. Abbott shall be permitted to change its funding obligations under Section 3.2 only as follows:

- (a) If in any Program Year Abbott spends on Program Related Costs, the full amount of the Program Payment provided by John Hancock for such Program Year, but does not spend the full amount of the Annual Minimum Spending Target for such Program Year (including any Annual Carryover Amounts from any prior Program Years), Abbott will spend on Program Related Costs the difference between its expenditure on Program Related Costs for such Program Year and the Annual Minimum Spending Target

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for such Program Year (the "Annual Carryover Amount") in the subsequent Program Year. John Hancock's obligation to make any Program Payment for such subsequent Program Year, if any, pursuant to Section 3.1, shall be deferred until the time that Abbott has spent and notifies John Hancock that it has spent the Annual Carryover Amount in such subsequent Program Year; and

- (b) If Abbott does not expend on Program Related Costs the full amount of the Aggregate Spending Target during the Program Term, Abbott will expend the difference between its expenditures for Program Related Costs during the Program Term and the Aggregate Spending Target (the "Aggregate Carryover Amount") on Program Related Costs during the subsequent year commencing immediately after the end of the Program Term. If Abbott does not spend the Aggregate Carryover Amount on Program Related Costs during such subsequent year, Abbott will pay to John Hancock one-third of the Aggregate Carryover Amount that remains unspent by Abbott, within thirty (30) days after the end of such subsequent year.

3.4 Termination of John Hancock's Program Payment Obligation. If Abbott: (i) abandons development of all Preclinical Programs and Program Compounds in any Program Year during the Program Term (it being understood that such abandonment need not occur entirely in one Program Year); (ii) does not expend on Program Related Costs during any Program Year the full amount of the Program Payment made by John Hancock for such Program Year; (iii) does not reasonably demonstrate in its Annual Research Plan, its intent and reasonable expectation to expend on Program Related Costs during the next Program Year an amount in excess of the Program Payment to be provided by John Hancock for such year; or (iv) does not reasonably demonstrate in its Annual Research Plan its intent and reasonable expectation to expend on Program Related Costs during the Program Term an amount in excess of the Aggregate Spending Target, John Hancock's obligation to make any remaining Program Payments for any succeeding Program Years pursuant to Section 3.1 shall terminate. For the avoidance of doubt, the Program Payments for the Program Year in which such event occurs shall still be due and payable, adjusted only as set forth in the next sentence, if applicable. In addition, in the case of either (i) or (ii) above, Abbott shall (not later than the 10th day following such event) pay to John Hancock (x) the amount, if any, by which the Program Payment made by John Hancock for such year (in the case of (i) above meaning the Program Year in which all Preclinical Programs and Program Compounds were finally abandoned), if any, exceeds one-half of the Program Related Costs actually spent by Abbott during that Program Year and (y) such additional amount that, after giving effect to the payments referred to in this sentence, causes the Program Related Costs for all years in the Program Term to date to have been funded one-third (1/3) by John Hancock and two-thirds (2/3) by Abbott.

3.5 Hancock Funding Obligation. John Hancock's entire obligation hereunder shall be limited to providing the Program Payments set forth in Section 3.1. Abbott shall be solely

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responsible for funding all Program Related Costs in excess of the Program Payments from John Hancock.

ARTICLE 4 PRODUCT RESEARCH AND DEVELOPMENT

4.1 Commercially Reasonable Efforts. Abbott shall be solely responsible for the clinical development, government approval, manufacturing, marketing, sales and distribution of Products. Abbott will use, and will cause each of its Affiliates and Licensees to use, Commercially Reasonable Efforts to pursue the clinical development, government approval, manufacturing, marketing, sales and distribution of Products throughout the Territory. The obligations of Abbott, its Affiliates and Licensees with respect to any Product under this Article 4 are expressly conditioned upon the safety, efficacy and commercial feasibility of each Product, consistent with using Commercially Reasonable Efforts, but no license, assignment or other transfer of rights by Abbott will modify or reduce Abbott's obligations hereunder (except as set forth in Article 14). It is the parties' expectation that under normal circumstances Abbott will file for Regulatory Approval with respect to each Product in Europe within two (2) years from the date of the NDA filing for such Product in the U.S. Territory and in Japan within five (5) years from such NDA filing date; provided, however, that these time frames may be extended or otherwise altered based upon unforeseen circumstances that legitimately impact such regulatory filings in such foreign jurisdictions.

4.2 Marketing and Sale Responsibility. Without limiting the generality of Section 4.1, within six (6) months of obtaining Regulatory Approval for a Product in a given country, Abbott, its Affiliates or Licensees shall commence to market and sell such Product in such country. Abbott's obligation to market and sell a Product shall not apply to a Product in any country if Abbott has not commenced or has ceased marketing and selling such Product in such country substantially on account of adverse business or financial conditions caused by the regulatory authorities or other governmental authorities of such country (including not commencing marketing and selling in a country where the regulatory authorities have price or reimbursement approval and the price or reimbursement approval or that proposed by the regulatory authorities or government authorities is unacceptable to Abbott) which causes the marketing and sale of such Product in such country to be contrary to the financial best interests of John Hancock and Abbott; provided, however, that Abbott, its Affiliates or Licensees shall commence or resume marketing and sale of such Product in such country as soon as reasonably practical after such adverse business or financial conditions cease to exist.

4.3 Failure of Program Compound to Progress.

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- (a) Preclinical Programs: ED Program, FTI Program and MMPI Program.
With respect to any Program Compound resulting from a Preclinical Program that Abbott ceases to develop past Phase I Clinical Trial (i.e., does not enter a Phase II Clinical Trial) (a "Failed Early Stage Program

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Compound"), for which Abbott or its Affiliates has or will have one or more other compounds in such respective Preclinical Program (which includes all in-licensed compounds not yet approved for marketing), the next compound to enter Phase I Clinical Trials from such Preclinical Program shall be considered a Program Compound in all respects hereunder, as of the date of the cessation of such Failed Early Stage Program Compound; provided however, with respect to each Preclinical Program, there shall be no more than three Program Compounds substituted under this Section 4.3(a) (for an aggregate maximum of nine (9) such substitutions for all Preclinical Programs). At the time a Preclinical Program becomes a Ceased Program, Abbott shall have no further obligation to provide a substitute for a Failed Early Stage Program Compound.

- (b) Failure of ABT-492 or ABT-510 to Yield a Compound that Enters a Phase II Clinical Trial. If (i) ABT-492 fails to enter a Phase II Clinical Trial, or (ii) ABT-510 fails to enter a Phase II Clinical Trial, then within six (6) months after the failure of the first such Program Compound to enter a Phase II Clinical Trial, Abbott shall substitute a compound in a Phase II Clinical Trial having a commercial value not less than that currently expected for ABT-492 and ABT-510, respectively (as of the date of execution of this Agreement).
- (c) Cessation as a Result of an Acquired Replacement Compound. If Abbott ceases or substantially ceases developing, marketing or selling any Program Compound (that is in Phase I or beyond) or Product (a "Ceased Compound"), and if such cessation or substantial cessation is a result of Abbott's acquisition of a Replacement Compound, then the Replacement Compound shall be considered a Program Compound and/or Product from the date of such acquisition and the Ceased Compound shall no longer be considered a Program Compound.

In the event that the Replacement Compound has been approved for marketing by the FDA and the Ceased Compound has not been approved for marketing by the FDA as of the date of such acquisition, Section 4.3(d) shall apply and the first paragraph of this Section 4.3(c) shall not apply.

In the event that the Ceased Compound has been approved for marketing by the FDA as of the date of such acquisition, John Hancock shall have the option, in its sole discretion, to have Abbott maximize the commercial value of the Ceased Compound pursuant to Section 4.3(d) instead of having the Ceased Compound be subject to this Section 4.3(c).

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- (d) Cessation for Reasons Other than Section 4.3(c). If a Program Compound (that is in Phase I or beyond) or Product becomes a Ceased Compound for any reason not as a result of the acquisition of a Replacement Compound as set forth in Section 4.3(c) above and provided that such Ceased Compound has commercial value, then
- (i) as soon as is practicable Abbott shall maximize the commercial value, if any, of the Ceased Compound to both parties by out-licensing or divesting such Ceased Compound to a third party; provided, however, if the out-licensing or divestiture of such Ceased Compound requires the approval of Taisho Pharmaceutical Co., Ltd. (in the case of Program Compound ABT-773), Eisai Co., Ltd. (in the case of Program Compound ABT-751) or Wakunaga Pharmaceutical Co., Ltd. (in the case of Program Compound ABT-492), pursuant to the respective In-License Agreement, and such entity does not grant such approval, then Abbott shall within a reasonable period of time but not more than three months substitute a compound (which shall thereupon become a "Program Compound") having at least the current and projected potential commercial value as such Ceased Compound;
 - (ii) John Hancock shall be permitted (but have no obligation) to assist in such out-license and/or divestiture effort; and
 - (iii) Abbott shall remunerate John Hancock based on the sales of such Ceased Compound by the third party that has acquired or licensed the Ceased Compound (the "Acquirer") in a manner most consistent with the allocation that would have applied hereunder had such Ceased Compound not been so out-licensed or divested, i.e., in accordance with the royalties and milestones payable hereunder. The appropriate royalty rate payable to John Hancock shall be determined by adding the Acquirer's Net Sales of the Ceased Compound to the total Net Sales of other Products.
- (e) Divestiture. Notwithstanding anything herein to the contrary, Abbott shall not divest or out-license any Program Compound (which shall mean a sale, license or other transfer by Abbott of the right to develop, market and sell any Product containing such Program Compound either (i) in all of North America or (ii) in the countries of Japan and/or the European Union that have at least two-thirds of the total population of Japan and the European Union), without John Hancock's prior written consent, which consent shall not be unreasonably withheld; provided however, if such Program Compound is being divested as a result of direction from the

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Federal Trade Commission to so divest, John Hancock's written consent shall not be required.

- (f) Notice and Information. Abbott shall promptly notify John Hancock upon occurrence of any decision by Abbott to cease or substantially cease developing, marketing or selling any Program Compound or Product. In addition, Abbott shall provide to John Hancock all information reasonably requested by John Hancock related to any Replacement Compound, Program Compound, or Product that is subject to the provisions of this Section 4.3.
- (g) Commercially Reasonable Efforts. Nothing in this Section 4.3 shall lessen any of Abbott's other obligations under this Agreement nor permit Abbott to perform in any manner that is not clearly consistent with using its Commercially Reasonable Efforts hereunder.

4.4 Arm's-Length. Abbott shall not research, develop, manufacture, market, sell, distribute, out-license or otherwise treat any Program Compounds or Products differently, as compared to any other Abbott compounds or products, on account of any of John Hancock's rights hereunder. Furthermore, all distribution agreements, licenses, out-licenses and other agreements relating to the research, development, manufacturing, marketing, sale, distribution, licensing, out-licensing or divestiture of and all other transactions involving any Program Compounds or Products to or with any third party (except to Abbott's Affiliates) shall be on arm's-length terms and conditions.

4.5 In-License Agreements. Abbott shall comply in all material respects with the terms and conditions of the In-License Agreements. Abbott shall not amend the In-License Agreements or waive any of its rights thereunder without John Hancock's prior written consent (such consent not to be unreasonably withheld), unless such amendment or waiver does not have and would not have a material adverse effect on John Hancock's interests hereunder. To the extent that Abbott or any of its Affiliates obtains the right to market, distribute or sell Products containing the Program Compound known as ABT-751 in the Eisai Territory, then sales by Abbott, its Affiliates and Licensees of such Products in such territory shall be included in all respects hereunder (including without limitation in Net Sales and the Territory).

ARTICLE 5 PROGRAM INVENTIONS

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5.1 Ownership. As between Abbott and John Hancock, all inventions, innovations, ideas, discoveries, technology, know-how, methods, data, applications and products (in each case whether or not patentable) arising from the Research Program or otherwise related to the Program Compounds (collectively, the "Program Inventions") shall be exclusively owned by or assigned to Abbott. Abbott shall not divest, out-license or otherwise transfer any of its right, title

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or interest in or to any Program Inventions which would prevent or impair Abbott's ability to fulfill its obligations to John Hancock under this Agreement.

5.2 Patent Prosecution and Maintenance. To the extent it owns a Program Invention or has the contractual right to pursue patent protection for a Program Invention, Abbott will use Commercially Reasonable Efforts to obtain patent protection for the Program Inventions in the Territory. As between Abbott and John Hancock, Abbott shall be responsible for all costs and expenses and control all decisions related to pursuing such patent protection, including the preparation, filing (foreign and/or domestic), prosecution, issuance and maintenance of patent applications or patents covering Program Inventions.

5.3 Enforcement. As between Abbott and John Hancock, Abbott shall have the sole right and authority to enforce the patents or any other rights arising from the Program Inventions (including without limitation the Patents) against any infringers. If Abbott initiates any action or lawsuit to enforce such patents or other rights, it shall be solely responsible for the cost and expense thereof. Abbott will promptly notify John Hancock at such time as it becomes aware of any infringement activities and of any such enforcement actions or lawsuit, and Abbott will provide information concerning them as reasonably requested by John Hancock. All moneys recovered upon the final judgment or settlement of any such action or lawsuit, less the out-of-pocket cost and expense thereof, shall be allocated between Abbott and John Hancock proportional to Abbott's lost profits and John Hancock's lost royalties as a result of such infringement.

ARTICLE 6

MILESTONE PAYMENTS TO JOHN HANCOCK

6.1 [Intentionally omitted].

6.2 Management Fee. On December 1, 2002, 2003 and 2004, Abbott shall pay to John Hancock a management fee, each of which shall be in the amount of Two Million Dollars (\$2,000,000).

6.3 Milestone Notification and Payments. Abbott shall promptly notify John Hancock of the occurrence any of the following events that give rise to Abbott's obligation to make a payment pursuant to this Section 6.3 (each, a "Milestone Payment"). Except as hereinafter limited, Abbott shall pay the following Milestone Payments to John Hancock in the amounts and at the times set forth below with respect to each Program Compound:

- (a) One Million Dollars (\$1,000,000) shall be paid within thirty (30) days after the allowance by the FDA of each Investigational New Drug Application for such Program Compound;

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- (b) Two Million Dollars (\$2,000,000) shall be paid within thirty (30) days after the initiation of each Phase I Clinical Trial with such Program Compound;
- (c) Three Million Dollars (\$3,000,000) shall be paid within thirty (30) days after the initiation of each Phase II Clinical Trial with such Program Compound;
- (d) Four Million Dollars (\$4,000,000) shall be paid within thirty (30) days after the initiation of each Phase III Clinical Trial with such Program Compound; and
- (e) Five Million Dollars (\$5,000,000) shall be paid within thirty (30) days after the filing of each NDA with the FDA for such Program Compound.

In addition, except as hereinafter limited, Abbott shall pay the following Milestone Payments to John Hancock in the amounts and at the times set forth below:

- (f) (i) Twenty Million Dollars (\$20,000,000) shall be paid within thirty (30) days after the Regulatory Approval of the first Product in the U.S. Territory;
- (ii) Ten Million Dollars (\$10,000,000) shall be paid within thirty (30) days after the Regulatory Approval of the second Product in the U.S. Territory; and
- (iii) Ten Million Dollars (\$10,000,000) shall be paid within thirty (30) days after the Regulatory Approval of third Product in the U.S. Territory.

The aggregate of Milestone Payments under Section 6.3(a), (b), (c), (d), and (e) for all Program Compounds shall be limited to Eight Million Dollars (\$8,000,000), and once such aggregate limit has been paid, no further payments shall be due and payable under Sections 6.3(a), (b), (c), (d) or (e).

The aggregate of Milestone Payments under Sections 6.3(a), (b), (c), (d) and (e) for all Program Compounds shall be limited to zero dollars (\$0) during the first Program Year, Two Million Dollars (\$2,000,000) during the second Program Year, and Six Million Dollars (\$6,000,000) during the third Program Year, and once such annual limit has been reached for these particular Program Years, no further payments shall be due under Sections 6.3(a), (b), (c), (d) and (e) for the remainder of such Program Year; provided that any amounts that would have been due to John Hancock but for such annual limits shall be paid in subsequent Program Years so long as the Program Compound to which it relates has not been abandoned, divested or out-licensed by Abbott, subject to the Eight Million Dollar (\$8,000,000) limitation set forth above. Subject to

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the limitations above, the Milestone Payments under Sections 6.3(a), (b), (c), (d) and (e) may be made more than once with respect to each Program Compound.

The aggregate of Milestone Payments under Section 6.3(f) for all Program Compounds shall be limited to Forty Million Dollars (\$40,000,000), and once such aggregate limit has been paid, no further payments shall be due and payable under Section 6.3(f). In addition, Milestone Payments under Section 6.3(f) shall not be paid more than once for any particular Program Compound.

Exhibit 1.40 sets forth the current stage of clinical development for each Program Compound.

ARTICLE 7 ROYALTIES

7.1 Royalty Rates. Subject to the limitation set forth below, Abbott shall pay to John Hancock royalties equal to the following percentages of Net Sales, aggregated on a yearly basis, of all Products in the Territory:

<u>Royalty percentage</u>	<u>Yearly Net Sales (in millions) of all Products in the Territory</u>
8.5% of those Net Sales	up to \$400
and then 4% of those Net Sales	in excess of \$400 up to \$1,000
and then 1% of those Net Sales	in excess of \$1,000 up to \$2,000
and then 0.5% of those Net Sales	in excess of \$2,000

Net Sales shall be aggregated yearly (i) in the case of the U.S. Territory, on a calendar year basis, together with (ii) in the case of the International Territory, on a December 1 to November 30 basis, in each case consistent with the determination of Quarterly Reporting Periods.

7.2 Royalty Term. The duration of the obligation to make royalty payments on each Product shall be determined on a country-by-country basis and shall last for the duration of the Royalty Term in each given country for such Product.

ARTICLE 8 ROYALTY REPORTS AND ACCOUNTING

8.1 Reports. Exchange Rates. With respect to every Quarterly Reporting Period for which Abbott is obligated to pay any royalty hereunder, Abbott shall furnish to John Hancock a single written report for such Quarterly Reporting Period within sixty (60) days after the end of such Quarterly Reporting Period (that is, within sixty (60) days after each March 31, June 30, September 30 and December 31, as the case may be) showing in reasonably specific detail:

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- (a) the total gross sales in each country for each Product sold by Abbott, its Affiliates and Licensees in the Territory and the detailed calculation of Net Sales from gross sales in each country for each Product;
- (b) the royalties payable in Dollars, if any, which shall have accrued hereunder;
- (c) the dates of the First Commercial Sale of each Product in any country in the Territory during such Quarterly Reporting Period; and
- (d) the exchange rates used in determining the amount of Dollars.

With respect to sales of Products invoiced in Dollars, the gross sales, Net Sales (including all adjustments and deductions permitted to be made hereunder in calculating the same), and royalties payable shall be expressed in Dollars. With respect to sales of Products invoiced in a currency other than Dollars, the gross sales, Net Sales (including all adjustments and deductions permitted to be made hereunder in calculating the same) and royalties payable shall be expressed in their Dollar equivalent, calculated using the Inter Bank rate set forth in the International Report published by International Reports Inc. as Foreign Exchange Rates quoted in New York on the day nearest the last business day of the Quarterly Reporting Period.

8.2 Audits.

- (a) Upon the written request of John Hancock and, in the absence of any breach by Abbott hereunder, not more than once in each calendar year, Abbott shall permit John Hancock and an independent certified public accounting firm of nationally recognized standing, selected by John Hancock and reasonably acceptable to Abbott, at John Hancock's expense, to have access during normal business hours to such of the records of Abbott, its Affiliates and Licensees to verify the accuracy of the royalty reports and the amounts and calculation of any payments required hereunder for any year ending not more than five (5) years prior to the date of such request.
- (b) If such accounting firm concludes that additional royalties or other payments were owed during such period, Abbott shall have the option to invoke the proceedings of Section 16.7 below or pay the additional royalties or other payments within thirty (30) days after the date John Hancock delivers to Abbott such accounting firm's written report so concluding. The reasonable fees and expenses charged by such accounting firm shall be paid by John Hancock; provided, however, if the audit discloses that the amounts payable by Abbott for any Quarterly Reporting Period are more than one hundred five percent (105%) of the royalties

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actually paid for such period, then Abbott shall pay the reasonable fees and expenses charged by such accounting firm.

- (c) Abbott shall cause its Affiliates to, and shall include in each license granted by it relating to a Program Compound or Product a provision requiring the Licensee to, (i) make reports to Abbott, (ii) keep and maintain records of Net Sales made pursuant to such license and (iii) grant access to such records by John Hancock and its accounting firm or other auditor to the same extent required of Abbott under this Agreement.
- (d) All reports and payments not disputed as to correctness by John Hancock within five (5) years after receipt thereof shall thereafter conclusively be deemed correct for all purposes, and Abbott, its Affiliates and Licensees shall be released from any liability or accountability with respect to such reports and payments.

8.3 Confidential Financial Information. John Hancock shall treat all information subject to review under this Article 8, and shall cause its accounting firm to agree to treat all such information, in accordance with the provisions of Article 10.

8.4 Accounting Principles. All accounting hereunder, including without limitation all determinations of gross sales, Net Sales (including all adjustments and deductions permitted to be made hereunder in calculating the same), Program Related Costs and all calculations underlying such determinations, shall be made in accordance with generally accepted accounting principles as in effect in the United States, consistently applied.

ARTICLE 9 PAYMENTS

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9.1 Payment Terms. With respect to every Quarterly Reporting Period for which Abbott is obligated to pay a royalty hereunder, such royalties shall be due and payable in a single payment within sixty (60) days of the end of such Quarterly Reporting Period (that is, within sixty (60) days of each March 31, June 30, September 30 and December 31, as the case may be). Payment of royalties may be made in advance of such due date.

9.2 Payment Method. All royalties and other payments by Abbott to John Hancock under this Agreement shall be made by bank wire transfer in immediately available funds in accordance with the instructions set forth on Exhibit 9.2 attached hereto or in accordance with such other instructions as John Hancock may give from time to time.

9.3 Late Payments. Each party shall pay interest to the other on the aggregate amount of any payments by it that are not paid on or before the date such payments are due under this Agreement, including, without limitation, any disputed payments or payments resulting from any

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audit, at a rate per annum equal to the lesser of (a) the prime rate of interest plus two hundred (200) basis points as reported by Citibank, N.A. in New York, from time to time (with any change in such reported rate being effective immediately for purposes hereof), or (b) the highest rate permitted by applicable law, calculated on the number of days such payments is delinquent until paid in full in cash. All such amounts shall be payable upon demand.

ARTICLE 10 CONFIDENTIALITY

10.1 Nondisclosure Obligations. Except as otherwise provided in this Article 10, during the term of the Agreement and for a period of ten (10) years thereafter, (a) John Hancock shall maintain in confidence in accordance with such procedures as are adopted by John Hancock to protect its own confidential information and shall use only for purposes of this Agreement (including, without limitation, enforcement of the terms hereof), information and data related to the Program Compounds or Products; and (b) John Hancock shall also maintain in confidence in accordance with such policies, and use only for purposes of this Agreement, all information and data supplied by Abbott under this Agreement, which if disclosed in writing is marked "confidential", if disclosed orally is promptly thereafter summarized and confirmed in writing to the other party and marked "confidential", or if disclosed in some other form is marked "confidential."

10.2 Permitted Disclosures. For purposes of this Article 10, information and data described in clause (a) or (b) above shall be referred to as "Confidential Information". John Hancock may disclose Confidential Information as required by applicable law, regulation or judicial process, provided that John Hancock shall, if legally permitted, give Abbott prompt written notice thereof. The obligation not to disclose or use Confidential Information shall not apply to any part of such Confidential Information that (i) is or becomes patented, published or otherwise part of the public domain other than by acts or omissions of John Hancock in contravention of this Agreement; or (ii) is disclosed to John Hancock by a third party, provided such Confidential Information was not obtained on a confidential basis by such third party from Abbott, its Affiliates or Licensees; or (iii) prior to disclosure under the Agreement, was already in the possession of John Hancock, provided such Confidential Information was not obtained directly or indirectly from Abbott, its Affiliates or Licensees under an ongoing obligation of confidentiality; or (iv) is disclosed in a press release agreed to by both parties under Section 10.3 below.

10.3 Publicity Review. Without the prior written consent of the other party, neither party shall make any statement to the public regarding the execution and/or any other aspect of the subject matter of this Agreement and John Hancock shall not make any statement to the public regarding any work under the Research Program; provided that, Abbott may make statements to the public regarding work done under the Research Program (without reference to or mention of John Hancock) and the commercialization of any Products resulting therefrom in accordance with its standard business practices. John Hancock and Abbott shall not disclose any

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terms or conditions of this Agreement to any third party without the prior consent of the other party, except as set forth above in this Section 10.3 or as required by applicable law, regulation or court order. The parties agree not to issue a press release announcing the execution of this Agreement.

ARTICLE 11
TERM AND TERMINATION

11.1 Expiration. This Agreement shall expire upon satisfaction of Abbott's obligations to pay royalties under Section 7.2 and all other amounts under this Agreement.

11.2 Termination; Material Breach. It is the parties' express intent that consideration shall be given to remedying any breach of this Agreement through the payment of monetary damages or such other legal or equitable remedies as shall be appropriate under the circumstances and that there shall only be a limited right to terminate this Agreement under the following circumstances.

- (a) In the event that the court, in accordance with the procedures set forth in Section 16.2, has issued a ruling that John Hancock has breached its obligation under Section 3.1 of this Agreement (obligation to make payments), and such ruling specified the actions to be taken by John Hancock on account of such breach, and John Hancock has failed to comply with the terms of such ruling within the time period specified therein for compliance and the time for any appeal has expired without the submission of an appeal, then, in addition to all other rights available to Abbott under law and equity, including its right to enforce such ruling in court, Abbott shall have the right to terminate the Agreement as a result of John Hancock's failure to abide by the terms of this Agreement and such ruling.
- (b) In the event that the court, in accordance with the procedures set forth in Section 16.2, has issued a ruling that Abbott has breached a material obligation under this Agreement, and such ruling specified the actions to be taken by Abbott on account of such breach, and Abbott has failed to comply with the terms of such ruling within the time period specified therein for compliance and the time for any appeal has expired without the submission of an appeal, then, in addition to all other rights available to John Hancock under law and equity, including its right to enforce such ruling in court, John Hancock shall have the right to terminate the Agreement, each as a result of Abbott's failure to abide by the terms of this Agreement and such ruling.

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11.3 Effect of Expiration or Termination. Expiration or, if applicable, termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination. The provisions of Articles 8 (Royalty Reports and Accounting), 10 (Confidentiality), 11 (Term and Termination), 12 (Warranties and Indemnification) and 16 (Miscellaneous) shall survive the expiration or termination of this Agreement.

ARTICLE 12 WARRANTIES AND INDEMNITY

12.1 John Hancock Representations and Warranties. John Hancock represents and warrants to Abbott that as of the Execution Date:

- (a) The execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate John Hancock corporate action. This Agreement constitutes John Hancock's valid and binding legal obligation, enforceable against it in accordance with its terms.
- (b) The performance by John Hancock of any of the terms and conditions of this Agreement on its part to be performed does not and will not constitute a breach or violation of its organizational documents or any other material agreement or understanding, written or oral, to which it is a party or any law, statute, rule or regulation by which it is bound.
- (c) No consent, approval, license or authorization of, or designation, declaration or filing with, any court or governmental authority is or will be required on the part of John Hancock in connection with the execution, delivery and performance by John Hancock of this Agreement or any other agreements or instruments executed and delivered by John Hancock in connection herewith or therewith, including, without limitation, any filings pursuant to federal or state securities laws or pursuant to any federal anti-trust laws.
- (d) Neither John Hancock nor any person acting on its behalf (i) has taken or will take any action which would subject this Agreement and the consummation of the transactions contemplated hereby to the registration or qualification requirements of any federal or state securities laws, (ii) has dealt with any broker, finder or other similar person in connection with the transactions contemplated by this Agreement or (iii) is under any obligation to pay any broker's fee, finder's fee or commission in connection with such transactions.

12.2 Abbott Representations and Warranties. Abbott represents and warrants to John Hancock that as of the Execution Date:

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- (a) The execution and delivery of this Agreement and the performance of the transactions contemplated hereby have been duly authorized by all appropriate Abbott corporate action. This Agreement constitutes Abbott's valid and binding legal obligation, enforceable against it in accordance with its terms.
- (b) The performance by Abbott of any of the terms and conditions of this Agreement on its part to be performed does not and will not constitute a breach or violation of its organizational documents or any other agreement or understanding, written or oral, to which it is a party or any law, statute, rule or regulation by which it is bound.
- (c) No consent, approval, license or authorization of, or designation, declaration or filing with, any court or governmental authority is or will be required on the part of Abbott in connection with the execution, delivery and performance by Abbott of this Agreement or any other agreements or instruments executed and delivered by Abbott in connection herewith or therewith, including, without limitation, any filings pursuant to federal or state securities laws or pursuant to any federal anti-trust laws, except those consents, approvals, licenses, authorizations, and other requirements imposed by governmental authorities (both U.S. and foreign) and such declarations and filings with governmental authorities (both U.S. and foreign) required in the normal course of pharmaceutical research, development, marketing and sale.
- (d) Set forth on Exhibit 12.2(d) is the full name, chemical name, detailed description of the stage of development and current status, for each Program Compound. Set forth on Exhibit 1.6 in each Annual Research Plan is a description of projected milestones and dates thereof, projected year of NDA filing, and projected costs to be incurred by Abbott during the Program Term, for each Program Compound. Such projections were prepared in good faith and with due care based on reasonable assumptions, and represent the reasonable estimate of Abbott based on information available as of the date of such projections and as of the date hereof; it being agreed that such projections do not constitute any warranty as to the future performance of the Program Compounds and that actual results may vary from such projections.
- (e) Set forth on Exhibit 12.2(e) is a list and description of all domestic and foreign patents, patent rights, patent applications and all patent applications that are in the process of being prepared that are owned by or registered in the name of Abbott, or of which Abbott is a licensee or in which Abbott has any right, which claim any of the Program Compounds (the "Patents"). Abbott solely owns all of the Patents, except as indicated

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on Exhibit 12.2(e). All of the material Patents have been duly filed in or issued by the United States Patent and Trademark Office or the equivalent foreign patent office identified on Exhibit 12.2(e), as the case may be, and have been properly maintained and renewed in accordance with all applicable laws and regulations. With respect to the Patents that it does not own, Abbott has an exclusive and valid license thereunder to develop, make, have made, use, market and sell (with the right to sublicense) the applicable Program Compounds in the entire Territory; provided however, (i) with respect to Italy, Abbott has such rights that are co-exclusive with Eisai Co. Ltd. for the Program Compound known as ABT-751 and (ii) with respect to Japan, Abbott has such rights that are co-exclusive with Taisho Pharmaceutical Co., Ltd. for the Program Compound known as ABT-773. Except with respect to the Preclinical Programs, to Abbott's knowledge, it is not necessary to obtain or license any patents, patent rights, inventions, copyrights, manufacturing processes, formulae, trade secrets, proprietary rights or know-how that it does not currently have in order to (i) develop, make, have made, use, market and sell the Program Compounds or (ii) conduct the Research Program as heretofore conducted and as proposed to be conducted. Except with respect to those Program Compounds that are the subject of In-License Agreements, the Program Compounds are owned exclusively by Abbott, free and clear of any liens or encumbrances of any other person and, to Abbott's knowledge, Abbott does not require the consent of any other person to develop, make, have made, use, market and sell the Program Compounds.

- (f) Except as set forth in Exhibit 12.2(f) (but in any event, as of the Execution Date, such matters are not, and could not reasonably be expected to be material), Abbott has not received any communications alleging that, and no claim is pending or, to the knowledge of Abbott, threatened to the effect that, the operations of Abbott with respect to the Research Program or the Program Compounds infringe upon or conflict with (or will infringe or conflict with) the asserted rights of any other person under any domestic or foreign patent, trademark, service mark, copyright, trade secret, proprietary right or any other intellectual property right, and, except for the Preclinical Programs, there is no material basis known to Abbott for any such claim (whether or not pending or threatened). No claim is pending or, to the knowledge of Abbott, threatened to the effect that any of the Patents are invalid or unenforceable by Abbott, and there is no material basis known to Abbott for any such claim (whether or not pending or threatened). The publication of any material technical information with respect to the Program Compounds developed by and belonging to Abbott is subject to review and approval under Abbott's existing procedures.
- (g) Except for the In-License Agreements and customary employment and consulting agreements with Abbott's employees and consultants, there are

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no outstanding options, licenses, or agreements of any kind relating to the Patents or any of the Program Compounds or the transactions contemplated by this Agreement, which license the Patents or any technical information developed in the course of the clinical development program to any third party to register, market or sell any of the Program Compounds or Products.

- (h) To the knowledge of Abbott with respect to the Research Program and each of the Program Compounds, Abbott is not now, and in performing its obligations hereunder will not be, in any way making an unlawful or wrongful use of any confidential information, know-how, or trade secrets of any other person.
- (i) Neither this Agreement nor any Exhibit to this Agreement (including the compound reports attached as Exhibit 12.2(i) hereto (the "Compound Reports")) contains any untrue statement of material fact or omits to state any material fact necessary to make the statements contained herein or therein not misleading. There is no fact known to Abbott (other than generally available information concerning the pharmaceutical industry in general) as of the date of this Agreement that has not been disclosed in this Agreement or any Exhibit to this Agreement which has resulted in, or could reasonably be expected to result in, a material adverse effect on the prospects or condition (including safety, efficacy, scientific viability or commercial) of the Research Program or any of the Program Compounds.
- (j) Neither Abbott nor any person acting on its behalf (i) has taken or will take any action which would subject this Agreement and the consummation of the transactions contemplated hereby to the registration or qualification requirements of any federal or state securities laws, (ii) has dealt with any broker, finder or other similar person in connection with the transactions contemplated by this Agreement or (iii) is under any obligation to pay any broker's fee, finder's fee or commission in connection with such transactions.
- (k) Other than generally publicized actions, proceedings or investigations concerning the pharmaceutical industry in general, there is no action, proceeding or investigation pending or, to the knowledge of Abbott, threatened which (i) questions the validity of this Agreement or any action taken or to be taken by Abbott pursuant thereto or (ii) which has resulted in, or could reasonably be expected to result in, a material adverse effect on the prospects or condition (including safety, efficacy, scientific viability or commercial) of the Research Program or any of the Program Compounds.

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- (l) With respect to the Research Program and each of the Program Compounds, Abbott has (and in the future will have) obtained, to the extent permitted by law, from each of its employees, consultants, Affiliates and Subcontractors an agreement that reasonably protects Abbott's interest in the Program Inventions, Program Compounds and Products.
- (m) With respect to each Program Compound, since the date of its respective Compound Report, to the knowledge of Abbott, no condition, circumstance or fact has arisen (other than generally available information concerning the pharmaceutical industry in general) nor has Abbott made any change in the conduct of the Research Program which, individually or in the aggregate, has resulted in, or could reasonably be expected to result in, a material adverse effect on the prospects or condition (including safety, efficacy, scientific viability or commercial) of such Program Compounds.
- (n) Each In-License Agreement is valid, binding and in full force and effect, and there is no event which has occurred or exists, which constitutes or which, with notice and/or the passage of time, would constitute a material default or breach under any such contract by Abbott or, to Abbott's knowledge, any other party thereto, or would cause the acceleration of any obligation of any party thereto or give rise to any right of termination or cancellation thereof. Abbott has no reason to believe that the parties to each In-License Agreement will not fulfill their obligations thereunder in all material respects or that such parties do not have the right to grant the licenses granted thereunder. Abbott has no reason to believe that it will not fulfill its obligations under the In-License Agreements. Under the Eisai Agreement, neither Abbott nor its Affiliates has the right to market, distribute or sell Products containing the Program Compound known as ABT-751 in the Eisai Territory (with the exception of Italy).

12.3 No Conflict. Abbott and John Hancock represent and warrant that this Agreement does not, and will not, conflict with any other right or obligation provided under any other agreement or obligation that Abbott or John Hancock has with or to any third party.

12.4 Compliance with Law. Each party represents and warrants to the other that it will comply with all applicable laws, regulations and guidelines in connection with its performance of its obligations and rights pursuant to this Agreement, including the regulations of the United States and any other relevant nation concerning any export or other transfer of technology, services or products.

12.5 No Other Warranties. EACH PARTY TO THIS AGREEMENT AGREES THAT, EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS OR

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WARRANTIES, AND EACH HEREBY DISCLAIMS ANY OTHER REPRESENTATIONS OR WARRANTIES MADE BY ITSELF OR ANY OF ITS OFFICERS, DIRECTORS, EMPLOYEES, AGENTS, FINANCIAL AND LEGAL ADVISORS OR OTHER REPRESENTATIVES, WITH RESPECT TO THE EXECUTION AND DELIVERY OF THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, NOTWITHSTANDING THE DELIVERY OR DISCLOSURE TO THE OTHER OR THE OTHER'S REPRESENTATIVES OF ANY DOCUMENTATION OR OTHER INFORMATION WITH RESPECT TO ANY ONE OR MORE OF THE FOREGOING.

12.6 General Indemnification of John Hancock. Abbott shall indemnify and hold John Hancock and its Affiliates, agents, directors and employees harmless, and hereby forever releases and discharges John Hancock and its Affiliates, agents, directors and employees, from and against all Losses related to or arising out of, directly or indirectly, (i) any negligence, recklessness or intentional misconduct of Abbott or its Affiliates, agents, directors, employees, Subcontractors, licensees (including Licensees) or sublicensees in connection with the Research Program, Program Compounds or Products, or (ii) any manufacture, use, storage, distribution or sale of the Program Compounds or Products by anyone, including without limitation all Losses related to any personal injury or death, or (iii) any breach by Abbott of its representations, warranties or obligations hereunder, or (iv) the consummation of the transactions contemplated hereby, except, in each case, to the extent any such Losses are the result of (A) any breach by John Hancock of its representations, warranties or obligations hereunder, or (B) any negligence, recklessness, or intentional misconduct by John Hancock or its Affiliates, agents, directors, employees.

12.7 Indemnification Relating to Certain In-Licensed Compounds. Abbott shall indemnify and hold John Hancock and its Affiliates, agents, directors and employees harmless, and hereby forever releases and discharges John Hancock and its Affiliates, agents, directors and employees, from and against all Losses to the extent related to or arising out of, directly or indirectly, the fact that Abbott's rights in the Program Compounds known as ABT-773, ABT-492 and ABT-751 and the Patents and other patent rights, copyrights, trade secret rights and other intellectual property rights related thereto arise from the Taisho Agreement, the Wakunaga Agreement or the Eisai Agreement respectively, rather than being owned by Abbott as with the other Program Compounds. Accordingly, by way of example and without limiting the foregoing, Abbott's indemnification obligation under this Section 12.7 will arise upon (i) any impairment of Abbott's ability to perform its obligations under this Agreement in the entire Territory as a result of Abbott's rights to the Program Compounds known as ABT-773, ABT-442 and ABT-751 arising from the Taisho Agreement, Wakunaga Agreement and the Eisai Agreement, respectively or (ii) a breach by Abbott or any other person of any of the In-License Agreements; except, in each case, to the extent any such Losses are the result of (A) any breach by John Hancock of its representations, warranties or obligations hereunder, or (B) any negligence, recklessness, or intentional misconduct by John Hancock or its Affiliates, agents, directors, employees.

12.8 Procedure. If John Hancock or any of its Affiliates, agents, directors or employees (each, an "Indemnitee") intends to claim indemnification under this Article 12, it shall

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promptly notify Abbott (the "Indemnitor") of any Loss or action in respect of which the Indemnatee intends to claim such indemnification, and the Indemnitor shall have the right to participate in, and, to the extent the Indemnitor so desires, to assume the defense thereof with counsel selected by the Indemnitor; provided, however, that an Indemnatee shall have the right to retain its own counsel, with the fees and expenses of such counsel to be paid by the Indemnitor, if representation of such Indemnatee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnatee and any other party represented by such counsel in such proceedings. The indemnity obligation in this Article 12 shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld unreasonably or delayed. The failure to deliver notice to the Indemnitor within a reasonable time after the commencement of any such action, if materially prejudicial to its ability to defend such action, shall relieve the Indemnitor of any liability to the Indemnatee under this Article 12 only to the extent arising from the tardiness or absence of such notice, but the omission so to deliver notice to the Indemnitor will not relieve it of any liability that it may have to any Indemnatee otherwise than under this Article 12. The Indemnatee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action, claim or liability covered by indemnification under this Article 12, at the expense of the Indemnitor.

12.9 Insurance. Abbott shall at its expense maintain, through self-insurance or otherwise, product liability insurance with respect to the development, manufacture, sale and use of Products and Program Compounds in such amounts and on such terms as Abbott customarily maintains with respect to its other similar products. Abbott shall maintain such insurance for so long as it continues to develop, manufacture or sell any Products or Program Compounds, and thereafter for so long as Abbott customarily currently maintains such insurance.

12.10 Acknowledgment. Abbott and John Hancock acknowledge that Abbott has not delivered or disclosed the contents of any of the In-License Agreements to John Hancock.

ARTICLE 13 FORCE MAJEURE

Neither party shall be held liable or responsible to the other party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected party including but not limited to fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omission or delays in acting by any governmental authority; provided that such affected party shall provide the other party with prompt notice of the circumstances surrounding such a material failure or delay, after which the parties will amend this Agreement upon terms and conditions that are mutually agreeable to equitably account to the party that does not so fail or delay.

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ARTICLE 14
ASSIGNMENT

Except as expressly provided hereunder, this Agreement may not be assigned or otherwise transferred, nor may any right or obligations hereunder be assigned or transferred by either party without the consent of the other party; and, in addition, both parties acknowledge and agree that the obligations of Abbott hereunder are personal to Abbott and that Abbott is uniquely qualified to perform them; provided, however, that either party shall be obligated to assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its business, or in the event of its merger or consolidation or change in control or similar transaction and in such event such party shall cause its successor or transferee in such transaction to assume all of the obligations of such party. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Notwithstanding the foregoing, John Hancock shall have the right to assign its rights (but not its obligation to make payments under Section 3.1) in whole or in part (provided that, any assignment in part shall mean an assignment of a pro rata share of the entirety of John Hancock's rights hereunder) without Abbott's consent (and following any such assignment all references to John Hancock herein shall include any such assignee), provided that: (i) each assignee of such rights must be a bank, insurance company or other institutional investor; (ii) there shall be no greater than five (5) assignees, (iii) if any such assignee is located outside the United States John Hancock shall notify Abbott at least sixty (60) days in advance, (iv) if any claim arises with respect to Abbott's failure to make payments, then during the term of the Research Program (but in any event not longer than four years from the date hereof), any such claim must be brought by John Hancock, and not an assignee. In soliciting potential assignees for such right to payments, John Hancock shall not disclose any Confidential Information hereunder to more than ten (10) potential assignees. Any potential assignee to whom John Hancock discloses Confidential Information must have executed a confidentiality agreement no less stringent than Article 10 hereof. Furthermore, if John Hancock plans to exercise its right of assignment hereunder, John Hancock shall first notify Abbott of such plans in writing. Abbott shall have the first right to negotiate the purchase of any such assignment rights. If within fifteen (15) days after receipt of such notice the parties have not agreed upon the principal terms of such arrangement or if within forty-five (45) days after receipt of such notice the parties have not executed a final written agreement reflecting such arrangement, then John Hancock shall have no further obligations to Abbott with respect to such first right of negotiation.

ARTICLE 15
SEVERABILITY

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Each party hereby agrees that it does not intend its execution and delivery hereof or its performance hereunder to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. If and to the extent any term or provision of this Agreement is held to be invalid, illegal or unenforceable by a court or other governmental

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authority of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement, which shall remain in full force and effect. The holding of a term or provision to be invalid, illegal or unenforceable in a jurisdiction shall not have any effect on the application of the term or provision in any other jurisdiction.

ARTICLE 16
MISCELLANEOUS

16.1 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the parties hereto to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by personal delivery, U.S. first class mail or courier), U.S. first class mail or courier, postage prepared (where applicable), addressed to such other party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

If to John Hancock: John Hancock Life Insurance Company
200 Clarendon Street, T-57
Boston, MA 02117
Attention: Bond & Corporate Finance Group
Telephone: 617-572-9624
Fax: 617-572-1628

copy to: John Hancock Life Insurance Company
200 Clarendon Street, T-50
Boston, MA 02117
Attention: Investment Law Division
Telephone: 617-572-9205
Fax: 617-572-9268

and, if it relates to making or not making a royalty payment or Milestone Payment hereunder,

copy to: John Hancock Life Insurance Company
200 Clarendon Street
Boston, MA 02117
Attention: Manager, Investment Accounting Division, B-3
Fax: 617-572-0628

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Leonard Deposition Exhibit 1

P's Exhibit 32

Part 2

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If to Abbott: Abbott Laboratories
Dept. 309, Bldg. AP30
200 Abbott Park Road
Abbott Park, IL 60064-3537
Attention: President, Pharmaceutical Products Division
Telephone: 847-938-6863
Fax: 847-938-5383

copy to: General Counsel
Abbott Laboratories
Dept. 364, Bldg. AP6D
100 Abbott Park Road
Abbott Park, IL 60064-6020
Telephone: 847-937-8905
Fax: 847-938-6277

16.2 Applicable Law. The Agreement shall be governed by and construed in accordance with the internal laws of the State of Illinois. With respect to any action hereunder, Abbott, to the extent that it may lawfully do so, hereby consents to service of process, and to be sued, in the Commonwealth of Massachusetts and consents to the exclusive jurisdiction of the courts of the Commonwealth of Massachusetts and the United States District Court for the District of Massachusetts, as well as to the jurisdiction of all courts to which an appeal may be taken from such courts, for the purpose of any suit, action or other proceeding arising out of any of its obligations hereunder or thereunder or with respect to the transactions contemplated hereby or thereby, and expressly waives any and all objections it may have as to venue in any such courts. Abbott further agrees that a summons and complaint commencing an action or proceeding in any of such courts shall be properly served and shall confer personal jurisdiction if served personally or by certified mail to it at its address for notices as provided in this Agreement or as otherwise provided under the laws of the Commonwealth of Massachusetts. THE PARTIES EACH IRREVOCABLY WAIVE ALL RIGHT TO A TRIAL BY JURY IN ANY SUIT, ACTION OR OTHER PROCEEDING INSTITUTED BY OR AGAINST IT IN RESPECT OF ITS OBLIGATIONS HEREUNDER OR THEREUNDER OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

16.3 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, with respect to the subject matter hereof heretofore made are expressly merged in and made a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both parties hereto.

16.4 Headings. The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.

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16.5 Independent Contractors. It is expressly agreed that John Hancock and Abbott shall be independent contractors and that the relationship between the two parties shall not constitute a partnership, joint venture or agency. Neither John Hancock nor Abbott shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other party to do so.

16.6 Performance By Affiliates, Licensees and Subcontractors. The parties recognize that Abbott may carry out certain obligations under this Agreement through performance by its Affiliates, Licensees and Subcontractors (but in no event shall that relieve Abbott of any of its obligations hereunder). Abbott guarantees that the activities of its Affiliates, Licensees and Subcontractors under this Agreement shall comply with this Agreement.

16.7 Dispute Resolution. The parties shall attempt to amicably resolve disputes arising between them regarding the validity, construction, enforceability or performance of the terms of this Agreement, and any differences or disputes in the interpretation of the rights, obligations, liabilities and/or remedies hereunder, which have been identified in a written notice from one party to the other, by good faith settlement discussions between the President of Abbott's Pharmaceutical Products Division and a Managing Director of John Hancock or his designee. The parties agree that, prior to filing any lawsuit regarding any dispute that arises in connection with this Agreement (with the exception of any action demanding a preliminary injunction), such representatives shall meet and attempt to amicably resolve such dispute within thirty (30) days after the receipt of such written notice.

16.8 Waiver. The waiver by either party hereto of any right hereunder or the failure to perform or of a breach by the other party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other party whether of a similar nature or otherwise.

16.9 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first set forth above.

JOHN HANCOCK LIFE
INSURANCE COMPANY

ABBOTT LABORATORIES

By: Stephen J. Blewitt
Name: Stephen J. Blewitt
Title: Managing Director
Date: March 13, 2001

By: Jeffrey M. Leiden
Name: Jeffrey M. Leiden, Ph.D., M.D.
Title: Executive Vice President, Pharmaceuticals
and Chief Scientific Officer
Date: March 13, 2001

JOHN HANCOCK VARIABLE
LIFE INSURANCE COMPANY

By: Stephen J. Blewitt
Name: Stephen J. Blewitt
Title: Authorized Signatory
Date: March 13, 2001

INVESTORS PARTNER LIFE INSURANCE
COMPANY

By: Stephen J. Blewitt
Name: Stephen J. Blewitt
Title: Authorized Signatory
Date: March 13, 2001

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EXHIBIT 1.6

FIRST ANNUAL RESEARCH PLAN

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JH 008116

Ketolide Oral & IV (ABT-773)
Annual Development Plan
Exhibit 1.6

Therapeutic Area	Antibacterial																																	
Indications	Adult Tablet: Community-acquired respiratory infections. I.V.: Step-down therapy in community-acquired hospitalized pneumonia.																																	
Description	<ul style="list-style-type: none">- ABT-773 is a potent ketolide with strong activity against most microbe resistant strains, while maintaining the broad spectrum coverage of clindamycin.- Product will be available as tablet and IV formulation.- ABT-773 will address the major unmet medical needs of increasing resistance to current empiric agents, particularly S. pneumoniae.- Maintains clari's claim of "Spans the spectrum" (G+, G-, atypicals).- Cover key G+ resistant strains (S. pneumoniae, S. pyogenes).- Tablet dosing is 150mg QD or 150mg BID dosing based on severity of indications.- Tablet: 8 days for ABECB, pharyngitis, 10 days for AMS and CAP.- Incidence of GI side effects equal to clari (assuming comparable drug levels to tablet).- COGS target \$2,600/kg at launch for tablet.																																	
	Current Time Line	<table><tr><th>Milestones</th><th>Tablet Date</th><th>IV Date</th></tr><tr><td>Phase I</td><td>1Q1997</td><td>1Q2001</td></tr><tr><td>Phase IIb</td><td>3Q1999</td><td>N/A</td></tr><tr><td>Phase III</td><td>4Q2000</td><td>4Q2001</td></tr><tr><td>NDA Filing</td><td>3Q2002</td><td>2Q2003</td></tr><tr><td>Launch</td><td>1Q2004</td><td>2Q2004</td></tr></table>					Milestones	Tablet Date	IV Date	Phase I	1Q1997	1Q2001	Phase IIb	3Q1999	N/A	Phase III	4Q2000	4Q2001	NDA Filing	3Q2002	2Q2003	Launch	1Q2004	2Q2004	<table><tr><th>Spending</th><th>\$</th></tr><tr><td>Project-to-Data-Spending (thru '00)</td><td>188.4</td></tr><tr><td>2001 Current Projection (Plan)</td><td>91.5*</td></tr></table>		Spending	\$	Project-to-Data-Spending (thru '00)	188.4	2001 Current Projection (Plan)	91.5*	* See page 2 for detail.	
Milestones	Tablet Date	IV Date																																
Phase I	1Q1997	1Q2001																																
Phase IIb	3Q1999	N/A																																
Phase III	4Q2000	4Q2001																																
NDA Filing	3Q2002	2Q2003																																
Launch	1Q2004	2Q2004																																
Spending	\$																																	
Project-to-Data-Spending (thru '00)	188.4																																	
2001 Current Projection (Plan)	91.5*																																	
Projected Spending by Year	<table><tr><th>2000</th><th>2001</th><th>2002</th><th>2003</th><th>2004</th><th>2005</th><th>Total</th></tr><tr><td>74.1</td><td>91.5</td><td>69.0</td><td>45.0</td><td>32.0</td><td>22.0</td><td>333.6</td></tr></table>										2000	2001	2002	2003	2004	2005	Total	74.1	91.5	69.0	45.0	32.0	22.0	333.6										
2000	2001	2002	2003	2004	2005	Total																												
74.1	91.5	69.0	45.0	32.0	22.0	333.6																												

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[illegible]

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Endothelin (ABT-627)
Annual Development Plan
Exhibit 1.6

Therapeutic Area	Oncology				
Indications	<ul style="list-style-type: none"> Hormone Refractory Prostate Cancer Potential for use in early Prostate Cancer and other cancer types ABT-627 is Abbott's leading endothelin antagonist receptor ABT-627 is seeking an indication for the treatment of hormone refractory prostate cancer ABT-627 will probably be used with current therapies Well tolerated as chronic therapy Oral administration No major drug interactions with drugs commonly used in elderly population or hormonal therapy Demonstrated cost effectiveness at filing 				
Description					
Current Time Line	Milestones	Date	Spending		
	Phase I	2Q1998	Project-to-Date-Spending (thru '00)		
	Phase II	4Q1997	2001 Current Projection (Plan)		
	Phase III	4Q2000	• See page 2 for detail.		
	NDA Filing	2Q2004			
	Launch	4Q2004			
Projected Spending by Year	2000	2001	2002	2003	2004
PC*	13.0	38.0	40.0	33.0	20.0
EPCA*	N/A	8.0	8.0	8.0	0.0
FE*	N/A	8.0	3.0	0.0	0.0
* End of Phase II meeting with FDA just completed. Budget impact still in process plus discussion of other cancer indications ongoing. 2001 range \$35-40 depending on outcome of discussion.					
			Total		
			154.0		
			17.0		
			8.0		

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CCM (ABT-594)
Annual Development Plan
Exhibit 1.6

Therapeutic Area		Neuroscience	
Indications		ABT-594 primary target indication is the treatment of neuropathic pain (NP).	
Description		<ul style="list-style-type: none"> - ABT-594 is a non-opioid, non-NSAID analgesic that is a potent and selective neuronal nicotinic receptor modulator. - ABT-594 is effective in nociceptive pain and neuropathic pain. - ABT-594 is expected to have a better side effect profile than opioids, no tolerance, no abuse, and no DEA scheduling. - Pre clinical data show ABT-594 to be 30 to 100 times more potent and equally efficacious to morphine in treating moderate to severe pain in several well characterized animal models of pain. - ABT-594 has a unique mechanism of action which may enable use in combination with other analgesics as well as monotherapy. - Slow onset of action (approx. 1.5 - 3 hours) at low doses tested may suggest limited utility in acute pain types. - Favorable safety profile. - Oral formulation, BID dosing. 	
Current Time Line	Milestones	Date	Spending
	IND Filing Phase I Phase II Phase III NDA Filing Launch	4Q1996 3Q1997 3Q1998 4Q2001 3Q2003 3Q2004	<div>Project-to-Date-Spending (thru '00)</div> <div>2001 Current Projection (Plan)</div> <div>97.3</div> <div>35.0*</div> <div>* See page 2 for detail.</div>
Projected Spending by Year		<div>2000</div> <div>14.4</div> <div>2001</div> <div>35.0</div> <div>2002</div> <div>45.0</div> <div>2003</div> <div>32.0</div> <div>2004</div> <div>15.0</div> <div>2005</div> <div>12.0</div> <div>Total</div> <div>151.4</div>	

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2001 Plan Development Cost Summary

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JH 008122

Quinolone (ABT-492)
Annual Development Plan
Exhibit 1.6

Therapeutic Area	Anti-bacterial																							
Indications	<ul style="list-style-type: none">- Community acquired respiratory, nosocomial pneumonias, complicated and uncomplicated urinary tract and skin/soft tissue infections.- ABT-492 is a potent broad-spectrum quinolone with activity against Gram⁺, Gram⁻, and atypical pathogens, including most penicillin, macrolide, and quinolone resistant strains of S. pneumo.- Commercial objective is "Trovan-like" activity with "Lavanquin-like" safety.- Preliminary in-vitro safety assays suggest good safety profile.- Product will be available in tablet and injectable formulations.- Targeting QD dosing for both formulations (not confirmed).- Targeting 5-7 day dosing for most indications (not confirmed).- COGS at \$1,600-3,200/kg at launch pending chemistry optimization.																							
Description																								
Current Time Line	<table><tr><td>Milestones</td><td>Date</td></tr><tr><td>Phase I</td><td>4Q2000</td></tr><tr><td>Phase II</td><td>3Q2001</td></tr><tr><td>Phase III</td><td>3Q2002</td></tr><tr><td>NDA Filing</td><td>4Q2004</td></tr><tr><td>Launch</td><td>4Q2005</td></tr></table>	Milestones	Date	Phase I	4Q2000	Phase II	3Q2001	Phase III	3Q2002	NDA Filing	4Q2004	Launch	4Q2005					<table><tr><td>Spending</td><td>\$</td></tr><tr><td>Project-to-Date Spending (thru '00)</td><td>11.3</td></tr><tr><td>2001 Current Projection (Plan)</td><td>25.0*</td></tr></table>	Spending	\$	Project-to-Date Spending (thru '00)	11.3	2001 Current Projection (Plan)	25.0*
Milestones	Date																							
Phase I	4Q2000																							
Phase II	3Q2001																							
Phase III	3Q2002																							
NDA Filing	4Q2004																							
Launch	4Q2005																							
Spending	\$																							
Project-to-Date Spending (thru '00)	11.3																							
2001 Current Projection (Plan)	25.0*																							
						* See page 2 for detail.																		
Projected Spending by Year	<table><tr><td>2000</td><td>2001</td><td>2002</td><td>2003</td><td>2004</td><td>2005</td><td>Total</td></tr><tr><td>6.8</td><td>25.0</td><td>75.0</td><td>100.0</td><td>52.0</td><td>11.0</td><td>269.8</td></tr></table>	2000	2001	2002	2003	2004	2005	Total	6.8	25.0	75.0	100.0	52.0	11.0	269.8									
2000	2001	2002	2003	2004	2005	Total																		
6.8	25.0	75.0	100.0	52.0	11.0	269.8																		

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TSP (ABT-510)
Annual Development Plan
Exhibit 1.6

Therapeutic Area		Oncoology																					
Indications		Solid tumors such as lung, breast, ovary, bladder and pancreas.																					
Description		<ul style="list-style-type: none">- Thrombospondin peptide- Novel anti-angiogenesis agent- Parenteral dosing- ABT-510 is seeking an indication for the treatment of solid tumors- Mechanism may prevent the growth of tumors and prevent the spread of metastases by preventing or inhibiting the growth of nutrient supplying blood vessels																					
Current Time Line		<table><thead><tr><th>Milestone</th><th>Date</th></tr></thead><tbody><tr><td>DOC</td><td>4Q1998</td></tr><tr><td>Phase I</td><td>2Q2000</td></tr><tr><td>Phase II</td><td>4Q2001</td></tr><tr><td>Phase III</td><td>1Q2003</td></tr><tr><td>NDA Filing</td><td>1Q2005</td></tr><tr><td>Launch</td><td>1Q2006</td></tr></tbody></table>	Milestone	Date	DOC	4Q1998	Phase I	2Q2000	Phase II	4Q2001	Phase III	1Q2003	NDA Filing	1Q2005	Launch	1Q2006	<table><thead><tr><th>Spending</th><th>\$\$</th></tr></thead><tbody><tr><td>Project-to-Date-Spending (thru '00)</td><td>45.6</td></tr><tr><td>2001 Current Projection (Plan)</td><td>9.0*</td></tr></tbody></table>	Spending	\$\$	Project-to-Date-Spending (thru '00)	45.6	2001 Current Projection (Plan)	9.0*
Milestone	Date																						
DOC	4Q1998																						
Phase I	2Q2000																						
Phase II	4Q2001																						
Phase III	1Q2003																						
NDA Filing	1Q2005																						
Launch	1Q2006																						
Spending	\$\$																						
Project-to-Date-Spending (thru '00)	45.6																						
2001 Current Projection (Plan)	9.0*																						
		* See page 2 for detail.																					
Projected Spending by Year		<table><thead><tr><th></th><th>2000</th><th>2001</th><th>2002</th><th>2003</th><th>2004</th><th>2005</th><th>Total</th></tr></thead><tbody><tr><td></td><td>6.6</td><td>9.0</td><td>37.0</td><td>28.0</td><td>23.0</td><td>15.0</td><td>119.6</td></tr></tbody></table>		2000	2001	2002	2003	2004	2005	Total		6.6	9.0	37.0	28.0	23.0	15.0	119.6					
	2000	2001	2002	2003	2004	2005	Total																
	6.6	9.0	37.0	28.0	23.0	15.0	119.6																

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JH 008125

TSP (ABT-510)
2001 Plan Development Cost Summary

Program Status	1998		1999		2000		2001		2002		2003		2004		2005	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Phase I																
Phase II																
Phase III																
DDC																
																NDA
Major Development Activities and Costs																
Clinical Program																
Single Escalating Dose in Healthy Subjects									Start		End					2001 Plan Cost
Multiple Dose in Cancer Patients									Apr-2000		Sep-2000					\$945
IND Study									Feb-2000		Sep-2001					\$500
Other Studies / EVR									Jun-2001		Nov-2001					\$328
Phase-I Center																\$108
Venture Management																\$800
Data Management/Statistics																\$164
																\$2,845
Chemistry, Manufacturing, and Controls (CMC)																
Formulation / Analytical																2000 AGU Cost
																\$762
Drug Safety Support																
Ongoing Drug Safety support.																2000 AGU Cost
																\$1,808
Other Support Costs																
Discovery																2000 AGU Cost
Medical Affairs																\$1,202
Regulatory Affairs / Research Quality Assurance																\$5
Other / In-licensing Fees																\$68
																\$196
Total Program																\$6,600
																2001 Plan Cost
																\$2,664
																\$45
																\$37
																\$2,000

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JH 008126

MMPI (ABT-518)
Annual Development Plan
Exhibit 1.6

Therapeutic Area		Oncology																					
Indications		Solid tumors such as lung, ovarian, pancreas, breast, colorectal and bladder.																					
Description		<ul style="list-style-type: none">- Novel metalloproteinase inhibitor.- Cytostatic mechanism.- Oral dosing.- May prevent the growth of metastatic lesions and/or inhibit primary tumor growth.- Superior efficacy or side-effect profile to competitive agents.																					
Current Time Line	<table><tr><th>Milestones</th><th>Date</th></tr><tr><td>DDC</td><td>1Q2000</td></tr><tr><td>Phase I</td><td>1Q2001</td></tr><tr><td>Phase II</td><td>3Q2002</td></tr><tr><td>Phase III</td><td>4Q2003</td></tr><tr><td>NDA Filing</td><td>4Q2005</td></tr><tr><td>Launch</td><td>2Q2006</td></tr></table>	Milestones	Date	DDC	1Q2000	Phase I	1Q2001	Phase II	3Q2002	Phase III	4Q2003	NDA Filing	4Q2005	Launch	2Q2006	<table><tr><th>Spending</th><th>\$</th></tr><tr><td>Project-to-Date-Spending (thru '00)</td><td>40.0</td></tr><tr><td>2001 Current Projection (Plan)</td><td>7.0*</td></tr></table> <p>* See page 2 for detail.</p>	Spending	\$	Project-to-Date-Spending (thru '00)	40.0	2001 Current Projection (Plan)	7.0*	
Milestones	Date																						
DDC	1Q2000																						
Phase I	1Q2001																						
Phase II	3Q2002																						
Phase III	4Q2003																						
NDA Filing	4Q2005																						
Launch	2Q2006																						
Spending	\$																						
Project-to-Date-Spending (thru '00)	40.0																						
2001 Current Projection (Plan)	7.0*																						
Projected Spending by Year	<table><tr><th>Year</th><th>Spending</th></tr><tr><td>2000</td><td>5.0</td></tr><tr><td>2001</td><td>7.0</td></tr><tr><td>2002</td><td>31.0</td></tr><tr><td>2003</td><td>35.0</td></tr><tr><td>2004</td><td>26.0</td></tr><tr><td>2005</td><td>20.0</td></tr><tr><td>Total</td><td>124.0</td></tr></table>	Year	Spending	2000	5.0	2001	7.0	2002	31.0	2003	35.0	2004	26.0	2005	20.0	Total	124.0						
Year	Spending																						
2000	5.0																						
2001	7.0																						
2002	31.0																						
2003	35.0																						
2004	26.0																						
2005	20.0																						
Total	124.0																						

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MMPI (ABT-518)
2001 Plan Development Cost Summary

Program Status	1999				2000				2001				2002				2003				2004				2005				2006			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4				
Phase I																																
Phase II																																
Phase III																																
NDA																																

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Anti-Mitotic (ABT-751)
Annual Development Plan
Exhibit 1.6

Therapeutic Area Indications	Oncology				
Description	Solid tumors such as breast, lung, colorectal, and ovarian				
	<ul style="list-style-type: none"> - Novel oral cytotoxic agent that inhibits tumor growth by inhibiting the polymerization of tubulin, similar to the MOA of taxanes - May be effective in patients resistant to other cytotoxic agents 				
Current Time Line	Allegations In-License	Date	Spending		
	Phase I Phase II Phase III NDA Filing Launch	2Q2000 1Q/2001 4Q/2001 4Q/2002 1Q/2005 1Q/2006	Project-to-Date-Spending (thru '00) 2001 Current Projection (PLAN) * See page 2 for detail.		
Projected Spending by Year	2000	2001	2002	2003	2004
	6.0	10.0	27.0	35.0	25.0
					Total
					115.0

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Anti-Mitotic (ABT-751) 2001 Plan Development Cost Summary

Program Status		1998				1999				2000				2001				2002				2003				2004			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4				
Phase I																													
Phase II																													
Phase III																													

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FTI (ABT-xxx)
Annual Development Plan
Exhibit 1.6

Therapeutic Area		Oncology						
Indications		Solid tumors such as lung, breast, ovary, bladder and pancreas. - Farnesyltransferase Inhibitor. - Mechanism of action is unknown, but thought to inhibit farnesylated proteins which are integral for malignant tumor growth.						
Description		Spending						
Current Time Line		Milestones	Date	Project-to-Date Spending (thru '00)				
		DOC	1Q/2001	35.0				
		Phase I	4Q/2001	6.0*				
		Phase II	2Q/2003	2001 Current Projection (Plan)				
		Phase III	3Q/2004	* See page 2 for detail.				
		NDA Filing	4Q/2006					
		Launch	4Q/2007					
Projected Spending by Year		2000	2001	2002	2003	2004	2005	Total
		N/A	6.0	15.0	30.0	30.0	18.0	99.0

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2001 Plan Development Cost Summary																											
Program Status		2000			2001			2002			2003			2004			2005			2006			2007				
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4		
Phase I	↑																										
Phase II																											
Phase III																											
	DDC																										
																			</								

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Dopamine Receptor Agonist (ABT-xxx)
Annual Development Plan
Exhibit 1.6

Therapeutic Area	Other		Male Erectile Dysfunction (MED)				
Indications			<ul style="list-style-type: none">- D4 Dopamine Receptor Agonist.- Targets D4 receptors in the brain which offers the potential for efficacy in patients with MED that do not respond to Viagra.- Additionally this approach offers opportunity for compounds with improved tolerability relative to other Dopamine agents that are clinically used for MED.				
Description	Milestones		Date		Spending		
	Current Time Line		DDC		Project-to-Date-Spending (thru '00)		
		Phase I		4Q/2001		38.0	
		Phase II		2Q/2002			
		Phase III		4Q/2003			
		NDA Filing		1Q/2005			
		Launch		1Q/2007			
				4Q/2007			
					2001 Current Projection (Plan)		6.0*
					* See page 2 for detail.		
Projected Spending by Year	2000	2001	2002	2003	2004	2005	Total
	N/A	8.0	15.0	30.0	30.0	18.0	99.0
CONF JH							

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Dopamine Receptor Agonist ABT-xxx
2001 Plan Development Cost Summary

2001 Plan Development Cost Summary																																	
Program Status		2000				2001				2002				2003				2004				2005				2006				2007			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4				
Phase I																																	
Phase II																																	
Phase III																																	

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Pharmaceutical Products Division
Sample Direct/Indirect Project Funding Distribution
2001 Plan (\$000)

	ABT - 773 (Late Stage - Phase III)			MMPI (Early Stage)		
	Direct	Indirect	Total	Direct	Indirect	Total
PPD Investigational Drug	0.3	0.0	0.4	-	-	-
Venture Management	4.8	1.6	6.5	0.8	0.2	0.9
Discovery	2.2	0.2	2.4	1.1	0.3	1.3
Drug Safety	1.6	0.2	1.7	1.8	0.3	2.1
PARD	4.8	0.4	5.3	0.8	0.2	1.0
Phase I Center	2.0	0.1	2.1	0.1	0.0	0.1
Development Operations	4.2	0.5	4.6	0.1	0.0	0.1
Regulatory Affairs	0.2	0.0	0.3	0.0	0.0	0.0
Medical Affairs	0.8	0.1	0.9	0.0	0.0	0.0
Administration	1.6	-	1.6	0.1	-	0.1
AI Manpower	0.7	-	0.7	-	-	-
Bulk Drug / Process	15.0	-	15.0	-	-	-
Clinical Oranits	43.1	-	43.1	1.3	-	1.3
Total	81.4	3.2	84.6	6.2	0.9	7.1
% Split	96.2%	3.8%	100.0%	86.6%	13.4%	100.0%

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Pharmaceutical Products Division
Sample Direct/Indirect Rate & Headcount Distribution
2001 Plan

<u>Rate:</u>	<u>Data Management</u>	<u>Toxicology/Pathology</u>
Direct		
Payroll (Both PMP and Supv/Mgr)	6,577	5,277
Office Supplies	53	51
T & E	26	84
Sem/Edu	21	73
Supplies	41	440
Consultant	291	67
Printing	73	4
Clinical Tracking Costs	4,075	--
Depreciation	1,031	258
UNIX Based Support	3,453	921
Utilities	62	--
Floorspace	579	1,479
Housekeeping	23	--
Other	112	389
Sub-Total Direct	16,416	9,042
Indirect		
Patents & Trademarks	285	388
Corporate Indirect	697	949
PPD Indirect (Mgmt.)	337	458
Department Overhead	396	584
Other	46	62
Sub-Total Indirect	1,761	2,441
Total	18,177	11,483
% Direct	90%	79%
% Indirect	10%	21%
 <u>Headcount:</u>		
Direct Headcount	123 88%	53 88%
Indirect Headcount	17 12%	7 12%
Total Headcount	140	60
 Rate	92.06	135.42
Hours	1,600	1,600
Annual Rate	147,296	216,672

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EXHIBIT 1.17

EISAI TERRITORY

1. Bhutan
2. Brunei
3. Cambodia
4. People's Republic of China
5. Republic of China (Taiwan)
6. India
7. Indonesia
8. Japan
9. Democratic People's Republic of Korea (North Korea)
10. Republic of Korea
11. Laos
12. Macao
13. Malaysia
14. Mongolia
15. Myanmar
16. Nepal
17. Pakistan
18. Papua New Guinea
19. Philippines
20. Singapore
21. Sri Lanka
22. Thailand
23. Vietnam
24. Italy, co-exclusive rights with Abbott, unless Abbott exercises its rights under the terms of the Eisai Agreement to take an exclusive right to Italy.

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EXHIBIT 1.40

PROGRAM COMPOUNDS

<u>In-License Agreement</u>	<u>Program Compound</u>	<u>Development Phase</u>
Taisho	ABT-627 (Endothelin antagonist)	phase III
	ABT-773 (Ketolide antibiotic)	phase III
	ABT-594 (Cholinergic channel modulator)	late phase II
Wakunaga	ABT-492 (Quinolone antibiotic)	phase I
Eisai	ABT-751 (Antimitotic)	phase I
	ABT-510 (Thrombospondin peptide)	phase I
<u>Preclinical Programs:</u>		
FTI Program		late preclinical
ED Program		late preclinical
MMPI Program	ABT-518 (Matrix metalloproteinase inhibitor)	phase I

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EXHIBIT 1.43

EXAMPLE OF PROGRAM RELATED COSTS FOR ONE PROGRAM COMPOUND

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2001 KEY RATES									
	2000			2001			% Change		
	Rate	Hours	Annual Rate	Rate	Hours	Annual Rate	Hourly Rate	Total Hours	Annual Rate
DRUG SAFETY									
Toxicology/Pathology - PMP/TMP	121.52	1,680	204,154	135.42	1,600	216,672	11.4%	4.8%	6.1%
Metabolism/Microscopy - PMP/TMP	144.75	1,600	231,600	141.64	1,650	233,706	-2.1%	3.1%	0.9%
Comparative Medicine - PMP/TMP	115.60	1,768	204,381	116.88	1,850	216,228	1.1%	4.6%	5.8%
Strategic & Exploratory - PMP/TMP	121.52	1,680	204,154	173.56	1,600	277,696	42.8%	-4.8%	36.0%
PHASE I CENTER									
Pharmacokinetics 4PK -PMP/TMP	144.75	1,600	231,600	135.00	1,600	216,000	-6.7%	...	-6.7%
Clin. Res. MDs 42P - PMP	180.35	1,500	270,525
Clin Res. Spec. 420-PMP/TMP	113.59	1,700	193,103	123.75	1,700	210,375	8.9%	...	8.9%
PARC									
Prod Dev - PMP, TMP	108.54	1,800	195,372	116.71	1,800	210,078	7.5%	...	7.5%
IDS - PMP, TMP	160.80	1,600	257,280	162.11	1,600	259,376	0.8%	...	0.8%
DEV OPERATIONS									
Data Mgmt D433 - TMP/PMP	90.04	1,600	144,064	92.06	1,600	147,296	2.2%	...	2.2%
Stats - PMP/TMP	97.75	1,800	175,950	99.10	1,800	178,380	1.4%	...	1.4%
RA/QA									
RA/QA - PMP & TMP	125.50	1,600	200,800	134.49	1,600	215,184	7.2%	...	7.2%
DISCOVERY									
	137.65	1,800	247,770	142.91	1,800	257,238	3.8%	...	3.8%

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03/13/01 02:09:34 PM

2001 KEY RATES 201 123

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EXHIBIT 9.2

PAYMENT INSTRUCTIONS

Fleet Boston
ABA No. 011000390
Boston, Massachusetts 02110
Account of: John Hancock Life Insurance Co. Private Placement Collection Acct.
Account Number: 541-55417
On Order of: Abbott Laboratories -- Research Funding Agreement dated as of March 13, 2001

E-3235160

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Exhibit 12.2(d)

Further Information Regarding Program Compounds

COMPOUND	CHEMICAL NAME	CURRENT STAGE OF DEVELOPMENT
ABT-627 Endothelin antagonist	(2R,3R,4S)-4-(1,3-benzodioxol-5-yl)-1-[2-(dibutylamino)-2-oxoethyl]-2-(4-methoxyphenyl)-3-pyrrolidinecarboxylic acid	Phase III
ABT-773 Ketolide antibiotic	(3aS,4R,7R,9R,10R,11S,13R,15R,15aR)-4-ethyl-3a,7,9,11,13,15-hexamethyl-2,6,8,14-tetraoxo-11-[[[(2E)-3-(3-quinolinyl)-2-propenyl]oxy]tetradecahydro-2H-oxacyclotetradecino[4,3-d][1,3]oxazol-10-yl 3,4,6-trideoxy-3-(dimethylamino)-D-xyllo-hexopyranoside	Phase III
ABT-594 Cholinergic channel modulator	(2R)-azetidinylmethyl 6-chloro-3-pyridinyl ether hydrochloride	Phase II
ABT-492 Quinoline Antibiotic	potassium 1-(6-amino-3,5-difluoro-2-pyridinyl)-8-chloro-6-fluoro-7-(3-hydroxy-1-azetidiny)-4-oxo-1,4-dihydro-3-quinolinecarboxylate	Phase I
ABT-518 Matrix metalloproteinase inhibitor	(1S)-1-[(4S)-2,2-dimethyl-1,3-dioxolan-4-yl]-2-[(4-{4-(trifluoromethoxy)phenoxy}phenyl)sulfonyl]ethyl(hydroxy)formamide	Phase I
ABT-751 Antimitotic	N-[2-(4-hydroxyanilino)-3-pyridinyl]-4-methoxybenzenesulfonamide	Phase I
Farnesyltransferase inhibitor	N.A.	Pre-Clinical Program
Dopamine Receptor Agonist for Erectile Dysfunction	N.A.	Pre-Clinical Program

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EXHIBIT 12.2(e)

Certain Patent Information

ABT-627

COUNTRY	FILING DATE	PATENT NUMBER	STATUS	EXP. DATE
Australia	08/04/1995	711832	<i>Issued</i>	08/04/2015
Brazil	02/12/1997		<i>Pending</i>	
Canada	08/04/1995		<i>Pending</i>	
EP*	08/04/1995		<i>Pending</i>	
Hong Kong	07/15/1998		<i>Pending</i>	
Israel	08/10/1995		<i>Pending</i>	
Japan	08/04/1995		<i>Pending</i>	
Korea	08/04/1995		<i>Pending</i>	
Mexico	08/04/1995		<i>Pending</i>	
Philippines	08/17/1995		<i>Pending</i>	
USA	05/30/1995	5,767,144	<i>Issued</i>	06/16/2015

*Europe: Austria, Belgium, Great Britain, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland

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Exhibit 12.2(e) (Cont'd)

ABT-773
(Subject to Taisho Agreement)

COUNTRY	FILING DATE	PATENT NUMBER	STATUS	EXP. DATE
Argentina	09/03/1997		Pending	
Australia	09/02/1997		Pending	
Brazil	05/13/1997		Pending	
Brazil	09/02/1997		Pending	
Bulgaria	09/02/1997		Pending	
Belarus	09/02/1997		Pending	
China	09/02/1997		Pending	
Chile	09/04/1997		Pending	
Canada	09/02/1997		Pending	
Columbia	09/02/1997		Pending	
Czech Republic	09/02/1997		Pending	
EP*	09/02/1997		Pending	
Guatemala	08/29/1997		Pending	
Hong Kong	09/02/1997		Pending	
Croatia	09/03/1997		Pending	
Hungary	09/02/1997		Pending	
Indonesia	09/04/1997		Pending	
India	Pending-Black Box		Pending	
Israel	09/02/1997		Pending	
Japan	09/02/1997		Pending	
Korea	09/02/1997		Pending	
Mexico	09/02/1997		Pending	
Malaysia	08/26/1997		Pending	
Norway	09/02/1997		Pending	

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Exhibit 12.2(c) (cont'd)

ABT-773 (cont'd)
(Subject to Taisho Agreement)

COUNTRY	FILING DATE	PATENT NUMBER	STATUS	EXP. DATE
New Zealand	09/02/1997		Pending	
Philippines	09/02/1997		Pending	
Pakistan	10/13/1997	136010	Issued	10/13/2013
Poland	09/02/1997		Pending	
Romania	09/02/1997		Pending	
Russia	09/02/1997		Pending	
South Africa	08/20/1997	97/7474	Issued	08/20/2017
Singapore	09/02/1997		Pending	
Slovak Republic	09/02/1997		Pending	
Slovenia	09/02/1997	20023	Issued	09/02/2017
Saudi Arabia	02/10/1998		Pending	
Thailand	09/03/1997		Pending	
Turkey	09/02/1997	TR 01127 B	Issued	09/02/2017
Taiwan	09/05/1997		Pending	
UA	09/02/1997		Pending	
USA	07/03/1997	5,866,549	Issued	09/04/2016
Yugoslavia	09/02/1997		Pending	

*Europe: Austria, Belgium, Great Britain, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland

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EXHIBIT 12.2(e) (Cont'd)

ABT-594

COUNTRY	FILING DATE	PATENT NUMBER	STATUS	EXP. DATE
Australia	10/08/1993	687017	Issued	10/18/2013
Brazil	04/30/1997		Pending	
Canada	10/08/1993		Pending	
EP*	10/08/1993		Pending	
Hong Kong	12/10/1998		Pending	
Israel	10/04/1993	107184	Issued	10/04/2013
Japan	10/08/1993	3098035	Issued	10/08/2013
Korea	10/08/1993		Pending	
Mexico	10/08/1993		Pending	
Philippines	10/07/1993		Pending	
USA	06/07/1995	5,948,793	Issued	09/07/2016

*Europe: Austria, Belgium, Great Britain, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland

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EXHIBIT 12.2(e) (Cont'd)

ABT-492

(Subject to Wakunaga Agreement)

COUNTRY	FILING DATE	PATENT NUMBER	STATUS	EXP. DATE
Australia	09/24/1999		Pending	
Brazil	11/29/1999		Pending	
Canada	12/06/1999		Pending	
China	10/22/1999	1258674A	Issued	
Hong Kong				
EP*	12/08/1999	0992501	Issued	
Hungary	11/23/1999	9904389	Issued	
Republic of Korea	08/29/2000			
Mexico	10/14/1999		Pending	
Russian Federation	05/26/2000		Pending	
USA	06/10/1999		Pending	
Japan	10/06/1999	2000-136191	Issued	

*Europe: Austria, Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, Great Britain, Greece, Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal, Sweden

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EXHIBIT 12.2(e) (Cont'd)

ABT-510

COUNTRY	FILING DATE	PATENT NUMBER	STATUS	EXP. DATE
Argentina	05/21/1999		Pending	
Australia	05/21/1999		Filing in Process	
Brazil	05/21/1999		Filing in Process	
Bulgaria	05/21/1999		Filing in Process	
China	05/21/1999		Filing in Process	
Chile	05/20/1999		Pending	
Canada	05/21/1999		Filing in Process	
Columbia	05/21/1999		Pending	
Czech Republic	05/21/1999		Filing in Process	
EP*	05/21/1999		Filing in Process	
Hong Kong	05/21/1999		Filing in Process	
Hungary	05/21/1999		Pending	
India	05/21/1999		Filing in Process	
Israel	05/21/1999		Filing in Process	
Japan	05/21/1999		Filing in Process	
Korea	05/21/1999		Filing in Process	
Mexico	05/21/1999		Filing in Process	
Norway	05/21/1999		Filing in Process	
New Zealand	05/21/1999		Filing in Process	
Philippines	05/21/1999		Pending	
Poland	05/21/1999		Filing in Process	
South Africa	05/21/1999		Filing in Process	
Slovak Republic	05/21/1999		Filing in Process	
Saudi Arabia	05/21/1999		Pending	
Turkey	05/21/1999		Filing in Process	
Taiwan	05/21/1999		Pending	
USA	05/21/1999		Pending	

*Europe: Austria, Belgium, Great Britain, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland

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EXHIBIT 12.2(e) (Cont'd)

ABT-518

COUNTRY	FILING DATE	PATENT NUMBER	STATUS	EXP. DATE
Argentina	07/30/1998		Pending	
Australia	07/27/1998		Pending	
Brazil	07/27/1998		Pending	
Bulgaria	07/27/1998		Pending	
China	07/27/1998		Pending	
Chile	07/17/1998		Pending	
Canada	07/27/1998		Pending	
Columbia	07/29/1998		Pending	
Czech Republic	07/27/1998		Pending	
EP*	07/27/1998		Pending	
Hungary	07/27/1998		Pending	
Israel	07/27/1998		Pending	
Japan	07/27/1998		Pending	
Korea	07/27/1998		Pending	
Mexico	07/27/1998		Pending	
Norway	07/27/1998		Pending	
New Zealand	07/27/1998		Pending	
Philippines	07/27/1998		Pending	
Poland	07/27/1998		Pending	
South Africa	07/30/1998	98/6828	Issued	07/30/2018
Slovak Republic	07/27/1998		Pending	
Saudi Arabia	12/15/1998		Pending	
Turkey	07/27/1998		Pending	
Taiwan	07/31/1998		Pending	
USA	08/05/1998		Pending	

*Europe: Austria, Belgium, Great Britain, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland

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EXHIBIT 12.2(e) (Cont'd)

ABT-751
(Subject to Eisai Agreement)

COUNTRY	FILING DATE	PATENT NUMBER	STATUS	EXP. DATE
USA	08/08/1991	5,250,549	Issued	08/08/2011
		5,292,758		08/08/2011
Germany	08/07/1991	EP 472,053	Issued	08/07/2011
United Kingdom	08/07/1991	EP 472,053	Issued	08/07/2011
France	08/07/1991	EP 472,053	Issued	08/07/2011

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EXHIBIT 12.2(f)

COMMUNICATIONS

With respect to ABT-594, Abbott has received the following communications:

- ♦ Correspondence from Sibia Neurosciences, 505 Coast Blvd. South, Suite 300, La Jolla, CA 92037 (Sibia was acquired by Merck & Co., Inc. in August, 1999) including, most recently, a letter dated March 13, 1998.
- ♦ Correspondence from ICT Pharmaceuticals c/o Stadheim and Gear, Ltd., 400 North Michigan Ave., Chicago, IL 60611 including, most recently, a letter dated September 14, 2000.

The Sibia and ICT correspondence each refer to their patents on research tools.

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EXHIBIT 12.2(i)

Compound Reports

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ABT – 773

Descriptive Memorandum

February 2001

Abbott Laboratories

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ABT-773

Opportunity Overview

ABT-773 pertains to a promising new class of antibiotics known as ketolides. ABT-773 is likely to have activity against resistant strains of bacteria and will, therefore, compete effectively against currently marketed antibiotics. The compound is currently in Phase II/III trials. Phase III clinical trials began in Q4, 2000. ABT-773 has an expected U.S. launch date in Q1, 2004. Ex-U.S. launches are projected in 2004 for Europe and Japan.

Product features such as high efficacy, activity against resistant strains of bacteria and convenience should enable it to compete against both Zithromax and newer agents such as the quinolones. Dosing is expected to be once-a-day. A 5-day convenience pak at a competitive price will help maximize sales.

The US Market

The overall antibiotic market in the U.S. reached \$8.9 billion in sales in 1999. The tab/cap segment is the largest; sales in 1999 were \$5.7 billion. The I.V. and oral suspension segments are comparatively smaller; total sales topped \$2.1 and \$1.1 billion, respectively.

Tab/cap and oral suspension prescription volume had been declining 1-2% per year in the period of 1995-1998, due to more appropriate prescribing in the face of increasing resistance. However, total tab/cap prescription volume recovered in 1999 and grew 6.3%. Even in the face of negative pressure on antibiotic use, dollar sales in the U.S. have continued to increase, particularly in the tab/cap market. This is due to the trend of replacing relatively low-cost generic agents with higher priced premium antibiotics. The market is willing to bear higher costs for agents that satisfy unmet needs. The I.V. market has grown slightly in terms of sales, also being driven largely by the replacement of generic agents with more costly branded agents.

Macrolides, largely fueled by the gains of Zithromax, have seen significant growth in terms of both prescriptions and sales. Zithromax prescriptions far outnumber those of other competitors, while its sales have nearly surpassed those of the sales leader, Cipro. Historically, quinolones saw relatively limited use for community respiratory tract infections (RTIs) because of poor Gram-positive coverage and sub-optimal adverse event profiles. Newer quinolones such as Levaquin have been successful in achieving more widespread use by virtue of its improved activity and adverse event profile. Levaquin currently accounts for approximately 30% of the quinolone market share. It is anticipated that recent quinolone introductions (Avelox, Tequin) will build upon the RTI momentum established by Levaquin. The growth of the macrolide and quinolone classes has come largely at the expense of cephalosporins and generic agents such as erythromycin and penicillin.

The following table shows 1999 tab/cap sales and prescriptions by class/product

	Sales			TRXs		
	Sales (\$MM)	Share	CAGR ₉₅₋₉₉	TRXs (MM)	Share	CAGR ₉₅₋₉₉
Penicillins	\$148.3	2.6%	-1.0%	52.5	23.7%	-5.6%
Cephalosporins	\$980.9	17.2%	-5.8%	37.9	17.1%	-3.5%
Cefitin	\$383.9	6.7%	1.8%	5.0	2.3%	-1.0%
Cefzil	\$188.7	3.3%	12.5%	2.7	1.2%	11.3%
Other	\$408.3	7.1%	-14.7%	30.1	13.6%	-4.8%
Ext. Spec. Macrolides	\$1,595.6	27.9%	19.9%	36.1	16.3%	20.8%
Biaxin	\$690.5	12.1%	6.1%	11.3	5.1%	1.2%
Zithromax	\$891.1	15.6%	42.1%	24.4	11.0%	41.5%
Other	\$14.0	0.2%	21.0%	0.4	0.2%	53.0%
Quinolones	\$1,622.1	28.4%	17.0%	24.0	10.8%	11.7%
Cipro	\$902.5	15.8%	8.3%	14.1	6.4%	5.1%
Levaquin	\$628.4	9.3%	NA	7.0	3.1%	NA
Other	\$190.2	3.3%	-2.2%	3.0	1.3%	-6.4%
Augmentin	\$778.1	13.6%	17.8%	10.7	4.8%	11.8%
Other Classes	\$590.5	10.3%	-1.1%	60.4	27.3%	-4.1%
TOTAL TAB/CAP	\$5,715.4	100.0%	8.9%	221.5	100.0%	0.1%

U.S. Market Projections

Resistance to antibiotics is likely to increase, creating opportunities for new agents with activity against resistance. Physicians will be urged to choose agents with an appropriate spectrum of activity relative to the infection being treated. Resistance will increasingly become part of the promotional mix for emerging agents. The ability of an agent to treat resistant strains and the real or perceived ability to slow or prevent resistance development (mutation prevention concentration, low mutation frequency, structure-activity relationships, etc) may confer competitive advantage to such agents.

- Quinolones, which historically have seen limited use in community-acquired respiratory infections, will become a significant class in this segment as new agents from this class are launched that specifically target RTIs.
- The market will become more competitive as new agents enter both the community segment (ketolides, quinolones) as well as the nosocomial segment (oxazolidinones, streptogramins, evernimomycins, peptides, others).
- Several key branded antibiotics will lose patent exclusivity over the next three to five years.. This may create an opportunity in the pediatric market as the top three pediatric brands (Augmentin, Cefzil, Zithromax) are among those losing patent exclusivity.

Antiviral influenza and cold therapeutics, as well as an increasing number of antibacterial vaccines may have a negative impact on antibiotic prescriptions.

The Ex-U.S. Market

Ex-U.S. sales of antibiotics totaled \$11.7 billion in 1999. Tab/cap represents the largest segment, with sales of \$9.4 billion from 770 million total prescriptions. Total Rx growth has been flat, with a 1996-99 CAGR of 0.5%. The use of antibiotics is predicted to slowly decline due to more judicious use of antibacterials in the face of increasing bacterial resistance.

Ex-U.S., the quinolone class accounted for 8% of total tab/cap market prescriptions (62 million Rxs) and 13% of sales (\$1.2 billion). Ciprofloxacin is the market leader ex-U.S. with approximately 47% of the quinolone market Rxs (29 million Rxs) and 44% (\$530MM) of sales. Levofloxacin launched in many European markets in 1998/1999 and holds approximately 14% Rx share of the European quinolone market and 0.8% of the overall tab/cap market. Although grepafloxacin and trovafloxacin also launched in some European countries in 1999, both products were recently pulled from the market due to liver toxicity and other complications. Moxifloxacin launched in Germany in Q4 1999, but has not yet been approved in other markets. In Japan, levofloxacin launched in 1994 and still commands a 65% Rx share of the quinolone market and 10% of the Japanese tab/cap market overall. Japan accounts for approximately 80% of ex-U.S. levofloxacin sales (\$370MM).

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Scientific Rationale for ABT-773

The likely profile of ABT-773 justifies further development:

- ABT-773 pertains to a new class of antibiotics.
- Good activity against resistant Gram + organisms, particularly macrolide-resistant *S. pneumoniae*.
- Convenience, safety, and tolerability profile competitive with Z-pak.
- Oral Suspension and I.V. forms enabling penetration into pediatrics and hospital segments.

Clinical Studies

The safety and efficacy of ABT-773 in AECB were studied in a multi-center Phase II clinical trial conducted between January and April of 1999. Dosing regimens of 100mg TID and 200mg TID were tested. Of the 169 enrolled patients, 159 were clinically evaluable and 96 were both clinically and bacteriologically evaluable. The following chart summarizes the results.

Bacterial Eradication	ABT-773 100mg TID	ABT-773 200mg TID	Overall Eradication
<i>S. pneumoniae</i>	100% (13/13)	90% (9/10)	96% (22/23)
<i>M. catarrhalis</i>	100% (6/6)	100% (7/7)	100% (13/13)
<i>H. influenzae</i>	96% (23/24)	92% (24/26)	92% (47/50)
<i>H. parainfluenzae</i>	100% (6/6)	88% (7/8)	93% (13/14)

Clinical Response	ABT-773 100mg TID	ABT-773 200mg TID
Cure	96% (77/80)	92% (73/79)
Failure	4% (3/80)	8% (6/79)

Clinical and Bacterial Response	ABT-773 100mg TID	ABT-773 200mg TID
Cure	96% (46/48)	94% (45/48)
Failure	4% (2/48)	6% (3/48)

Adverse Events	ABT-773 100mg TID	ABT-773 200mg TID	Overall
Taste Perversion	5% (4/84)	8% (7/85)	6.5% (11/169)
Diarrhea	11% (9/84)	6% (5/85)	8% (14/169)
Nausea	2% (2/84)	2% (2/85)	2% (4/169)
Abdominal Pain	1% (1/84)	2% (2/85)	2% (3/169)
Headache	2% (2/84)	1% (1/85)	2% (3/169)
Rash	2% (2/84)	1% (1/85)	2% (3/169)
Dyspnea	2% (2/84)		1% (2/169)
Elev. Liver Funct. Test	1% (1/84)	1% (1/85)	1% (2/169)
Fever		2% (2/85)	1% (2/169)

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The safety and efficacy of ABT-773 in AECB were studied in a multi-center Phase IIb clinical trial from October 1999 to March 2000. Doses of 150mg QD, 300mg QD, and 600mg QD were tested. Of the enrolled subjects, 342 were clinically evaluable, and 169 were both clinically and bacteriologically evaluable. The following chart summarizes the results.

Bacterial Eradication	ABT-773 150mg QD		ABT-773 300mg QD		ABT-773 600mg QD		Overall Eradication	
<i>S.pneumoniae</i>	83%	(10/12)	90%	(9/10)	100%	(13/13)	91%	(32/35)
<i>M.cattarrhalis</i>	80%	(8/10)	92%	(12/13)	91%	(10/11)	88%	(30/34)
<i>H. influenzae</i>	94%	(17/16)	89%	(17/19)	83%	(19/23)	88%	(53/60)
Clinical Response								
Cure	87%	(98/113)	90%	(105/117)	90%	(101/112)		
Failure	13%	(15/113)	10%	(12/117)	10%	(11/112)		
Clinical & Bacteriological Response								
Cure	84%	(42/50)	88%	(49/56)	94%	(59/63)		
Failure	16%	(8/50)	12%	(7/56)	6%	(4/63)		
Adverse Events								
Taste Perversion	5%	(4/84)	19%	(25/129)	29%	(37/129)	17%	(66/384)
Diarrhea	13%	(16/126)	12%	(15/129)	21%	(27/129)	15%	(58/384)
Nausea	7%	(9/126)	13%	(17/129)	30%	(38/129)	17%	(64/384)
Vomiting	2%	(3/126)	3%	(4/1229)	11%	(14/129)	5%	(21/384)
Nausea & Vomiting	0	(0/126)	<1%	(1/129)	4%	(5/129)	2%	(6/384)
Abdominal Pain	4%	(5/126)	4%	(5/129)	4%	(5/129)	4%	(15/384)

The safety and efficacy of ABT-773 in Acute Bacterial Sinusitis (ABS) were studied in a multi-center Phase IIb clinical trial conducted from October 1999 to March 2000. Dosing regimens of 150mg QD, 300mg QD, and 600mg QD were tested. Of the 292 enrolled subjects, 246 were clinically evaluable. The following chart summarizes the results.

Bacterial Eradication	ABT-773 150mg QD		AB T-773 300mg QD		ABT-773 600mg QD		Overall Eradication	
<i>S.pneumonia</i>	3/3		8/8		9/12		20/23	
<i>M. cattarrhalis</i>	8/9		3/4		4/4		15/17	
<i>H. influenzae</i>	3/5		7/7		5/7		15/19	
<i>S.aureus</i>	1/1		1/1		3/4		5/6	
Clinical Response								
Cure	89%	(70/79)	83%	(70/84)	71%	(59/83)		
Failure	11%	(9/79)	17%	(14/84)	29%	(24/83)		
Adverse Events								
Taste Perversion	1%	(6/97)	14%	(14/98)	27%	(26/97)	14%	(41/292)
Diarrhea	6%	(6/97)	6%	(6/98)	17%	(16/97)	10%	(28/292)
Nausea	3%	(3/97)	12%	(12/98)	26%	(25/97)	14%	(40/292)
Vomiting	1%	(1/97)	6%	(6/98)	17%	(16/97)	8%	(23/292)

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The safety and efficacy of ABT-773 in community-acquired pneumonia (CAP) were studied in a multi-center Phase IIb clinical trial from October 1999 to March 2000. Dosing regimens of 300mg QD and 600mg QD were tested. Of the 187 enrolled subjects, 1248 were clinically evaluable, and 15 were both clinically and bacteriologically evaluable. The following chart summarizes the results.

Bacterial Eradication	ABT-773 300mg QD		ABT-773 600mg QD		Overall Eradication	
<i>S. pneumoniae</i>	87%	(13/15)	100%	(7/7)	91%	(20/22)
<i>M. catarrhalis</i>	75%	(6/8)	50%	(2/4)	67%	(8/12)
<i>H. influenzae</i>	100%	(9/9)	72%	(13/18)	81%	(22/27)
<i>M. pneumoniae</i>	93%	(13/14)	93%	(14/15)	93%	(27/29)
<i>C. pneumoniae</i>	95%	(19/20)	79%	(19/24)	86%	(38/144)
<i>L. pneumoniae</i>	100%	(3/3)	100%	(2/2)	100%	(5/5)
Clinical Response						
Cure	92%	(72/78)	80%	(56/70)		
Failure	8%	(6/78)	20%	(14/70)		
Clinical & Bacterial Response						
Cure	92%	(54/59)	82%	(47/57)		
Failure	8%	(5/59)	18%	(10/57)		
Adverse Events						
Taste Perversion	17%	(16/95)	26%	(24/92)	21%	(40/187)
Diarrhea	14%	(13/95)	19%	(17/92)	16%	(30/187)
Nausea	12%	(11/95)	22%	(20/92)	17%	(31/187)
V omitting	10%	(9/95)	15%	(14/92)	12%	(23/187)

• Appendix 1

Key Emerging Competitors

Generic	Brand	Company	Class	Status
moxifloxacin	Avelox	Bayer	Quinolone	Approved by FDA 12/13/00
galifloxacin	Tequin	BMS	Quinolone	Approved by FDA 12/21/00
gemifloxacin	Factive	SKB	Quinolone	Filed NDA 12/15
T-3811	TBD	BMS/Toyama	Quinolone	Phase I
telithromycin	Ketek	Aventis	Ketolide	Filed NDA 3/00
linezolid	Zyvox	Pharmacia	Oxazolidinone	Approved by FDA Q2 '00

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ABT – 627

Descriptive Memorandum

February 2001

Abbott Laboratories

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JH 008159

ABT-627

Opportunity Overview

ABT-627 is an orally bioavailable endothelin antagonist with a high selectivity for the Eta receptor. The endothelins (ET-1, ET-2, ET-3) are a family of 21 amino acid peptides first identified in 1988. Endothelin is a potent, long acting vasoconstrictor produced by vascular endothelial cells. The known biological effect of ET-1 are believed to be mediated principally through the Eta receptor. These include potent and uniquely sustained vasoconstriction of vascular smooth muscle, positive inotropy of myocardium, and the stimulation of cell proliferation or the hypertrophy in vascular smooth muscle cells, cardiac myocytes, and fibroblasts.

In vitro studies in cultured cells have established that ABT-627 selectively binds to the Eta receptor, and that ABT-627 is a potent inhibitor of ET-1 binding to the Eta receptor.

Studies in cultured human prostate cancer cells and other cultured cells have shown that ABT-627 acts as a functional antagonist of ET-1, and these effects have been confirmed in vivo by assessing the effect of ABT-627 on the ET-1 induced pressor response in rats. Further animal studies have suggested that oral ABT-627 may be effective in the treatment of congestive heart failure, pulmonary hypertension, hypertension, arterial restenosis, and myocardial infarction.

In addition to literature and animal models supporting the role of endothelin antagonists in cardiovascular indications, data exists supporting the role of the ET-1 cytokine as a pathogenic mediator in cancer.

The current role of endothelin in the manifestations of metastatic prostate cancer (PCA) and other tumors have yet to be fully defined. However, Abbott scientists and thought leaders have made multiple observations about endothelin biology which suggest that endothelin may play a role in the biology and pathophysiology of metastatic prostate disease and other metastatic disease such as ovarian, cervical and renal tumors

ABT-627 has successfully completed Phase II trials for PCA, and the results demonstrate efficacy in hormone refractory PCA. The end of Phase II meeting with the FDA was held on October 4th. The data from Phase II was very favorably received and "best package" comments were made. Fast track designation and rolling NDA were granted. The FDA was conceptually in agreement with preliminary design of Phase III clinicals and clinical end points to measure. While not a dictate, a second Phase III trial will likely be conducted to insure the best opportunity for a successful outcome. The Phase III program is scheduled to commence before year-end. It is expected that filing on ABT 627 will occur in US and ex-US 1Q 2004. The compound is also in Phase I trials for other cancer types. Phase II studies in other cancer types will commence in 2Q01. Other indications outside of oncology are also being considered, to optimize the commercial potential of this asset.

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The US Market

Prostate cancer is the most common cancer to strike nonsmoking men. The NCI estimates that there are over 1.7 million men living with prostate cancer in the U.S., and another 179,300 will be diagnosed in 1999. Nearly 80% of these cases are men over 60 years of age. It is estimated that the prevalence of prostate cancer is 380,000 in Western Europe and 45,000 in Japan. While the vast majority of these patients will be identified with potentially curable disease (25% in Stage I and 50% in Stage II) in the U.S., half of these patients will go undiagnosed until late stage disease in W. Europe and Japan. The skewed distribution of diagnosed cases ex-U.S. is largely due to less aggressive prostate cancer screening programs compared to the U.S.

Prostate cancer has seen few additions or innovations in treatment regimens in the past two decades. Treatments remain, in general, radical prostatectomy (RP) for localized disease, radiotherapy for locally advanced disease and hormone therapy for advanced disease. Patients receiving hormone therapy become refractory to this treatment after two to three years, although many will continue on hormone therapy. These hormone refractory prostate cancer (HRPCa) patients usually have a life expectancy of approximately 12 months, and no existing standard of care exists for treating these patients. No therapy has shown a significant impact on survival in these patients, although some chemotherapeutic regimens may offer promise.

There is a general trend toward using hormone therapy in earlier stage patients. In some centers, patients are receiving hormone therapy prior to surgery or radiation, in an attempt to improve outcomes in these definitive treatments. Some thought leaders suggest that this earlier utilization has contributed to the overall mortality improvements in PCA. Studies are ongoing looking at different uses for hormone therapy, including intermittent therapy, in an attempt to improve outcomes and mitigate the morbidity associated with hormonal therapy.

Hormone therapy remains the mainstay of prostate cancer treatment in earlier stages. Chemotherapy, however, has gained additional attention in hormone refractory disease as new combinations and regimens offer the potential for greater therapeutic benefit with fewer side-effects. This trend will take several years before clinical trials are completed and community based oncologists adopt these regimens, so the current cytotoxic market in PCA is small.

The total dollar growth of this market has slowed as the two market leaders, Lupron (leuprolide/TAP) and Zoladex (goserelin/Zeneca), have experienced increased price pressures from managed care and Medicare. About half the states are currently reimbursing these therapies at a least cost option (only paying for the cheapest alternative), putting downward price pressures on Lupron (\$6,500/yr) to match Zoladex's (\$4,500/yr) lower price point. Thus, US Lupron dollar sales declined between 1997 and 1998, despite an increase in patient volume.

Growth has also stagnated due to a lack of innovation in this hormone dominated category. There have been few therapeutic advances in the treatment of PCA in the last 5 years.

The only chemotherapy approved for use in HRPCa patients with pain is Novantrone (mitoxantrone/Immunex), but the marginal benefits this compound delivers is deeply undercut by its severe toxicities and a lifetime cap on dose. Novantrone and steroids significantly reduced the metastatic pain in 40% of patients, but it does not appear to provide a survival advantage. Novantrone is dosed by i.v. infusion every 21 days, at a cost of \$560 per treatment, or an annual cost of around \$8,000. Use of this agent is associated with significant side-effects, including myelosuppression, cardiac toxicity (which limits dosing) and nausea. It is this negative side-effect profile that inhibits the use of this agent in more patients. Only about 4% of U.S. HRPCa patients received Novantrone therapy in 1998. Novantrone has not been approved ex-US.

Only about 17% of HRPCa patients received any chemotherapy in 1998. The most common drugs included estramustine, paclitaxel and eloposide. These drugs continue to be some of the most studied compounds in HRPCa ongoing research and represent the greatest short-term promise in the cytotoxic treatment of this advanced disease state.

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US Sales of Products to Treat Prostate Cancer

Product	1997 Dollar Sales (MM)	1998 Dollar Sales (MM)	% chng '97-'98
Lupron (leuprolide/TAP)	\$650	\$667	2.6%
Zoladex (goserelin/Zeneca)	233	296	27.3
Casodex (bicalutamide/Zeneca)	58	68	17.24
Euflexen (flutamide/Schering)	74	67	-9.5
Novantrone (mitoxantrone/Immunex)	33	35	6.1
Nilandrone (nilutamide/Hoechst)	12	24	100
Emcyt (estramustine/Pharmacia/Upjohn)	8	14	75
Taxol (paclitaxel/BMS)	4	8	100
VePesid (eloposide/BMS)	5	4	-20
Others	27	31	14.8
Total	1,104	1,214	10%

Source: Tandem Research and Price Probe

US Market Projections

- Novantrone (mitoxantrone/Immunex) is currently the only product approved for the treatment of hormone refractory PCA with pain. It currently falls short on the market needs in terms of efficacy and side-effect profile.

Attribute	Novantrone Profile
Dosing	I.V. infusion cycles
Cost	Expensive, ~\$10,000/yr
Efficacy	Provides marginal improvements in quality of life
Reimbursed	Yes
Side-effects	Dose limiting toxicities
Promo Efforts	108 oncology reps
Targets	Oncologists

Several surveys indicate that there are over 100 compounds in preclinical and clinical development for prostate cancer and various solid tumors. The compounds listed in the appendix represent compounds that appear to offer the greatest promise and/or potential for competition for ABT-627. However, since the most likely use of ABT-627 will be in combination with best therapy, it is difficult to define the extent of competitive threat that any of these compounds represent. In general, other cytostatic agents probably offer the greatest threat as a replacement for ABT-627. However, even other cytostatic agents may be combined to maximize the activity of the various mechanisms.

To date, PPD is aware of only one other endothelin receptor antagonist in development for cancer, from Yamanouchi, which began Phase I studies in the Fall of 1999. ABT-627 is still poised to be the first endothelin receptor antagonist to reach the market for oncology.

Scientific Rationale for ABT-627

There are relatively low hurdles for entry for a product to treat hormone refractory prostate cancer, as no truly effective agents presently exists. Quality of life is paramount in this population, followed by improvements in disease progression and survival. Quality of life parameters could include an impact on pain/or delay in pain onset or other performance type measures of daily activities. As all hormone therapy ultimately fails, a product that delays disease progression is needed.

Unmet Need	Pipeline Impact
Improvements in QOL	<ul style="list-style-type: none"> ABT-627's profile goal is to provide improvements to a patient's QOL or blunt a decrease in QOL Cytotoxic agents rarely have significant positive impacts on QOL Other cytostatic agents may offer this benefit
Improvements in survival	<ul style="list-style-type: none"> It is unlikely that improvements in survival will be seen in our current trials Cytotoxic agents may offer a survival advantage, perhaps in combination with ABT-627
Improvements in time to disease progression	<ul style="list-style-type: none"> Cytostatic and cytotoxic agents offer the greatest promise for this benefit

Our objective is to provide physicians and patients with a novel option for the treatment of hormone refractory prostate cancer, distinguish ABT-627 from current cytotoxic therapies and encourage the treatment of advanced prostate cancer patients currently only receiving hormonal therapy.

ABT-627 will be positioned as a physician and patient-friendly choice for advanced prostate cancer patients who have failed hormone therapy. ABT-627's novel mechanism of action provides a delay in disease progression and a positive impact on QOL. The oral, QD dosing enhances compliance and minimizes disruptions to daily living.

The message will focus on 3 key attributes:

- Efficacy (defined as increased time to tumor progression) in a patient group with few options
- Improvements in quality of life
- Convenience

Physicians no longer have to choose between *treating* advanced prostate cancer patients and a patient's quality of life. ABT-627 has a positive impact on disease progression and symptoms associated with quality of life, without the baggage of significant side-effects or the inconvenience of parenteral administration associated with current therapy choices.

This message expresses the key features of the agent in terms of patient benefits, as opposed to emphasizing the scientific/clinical aspects. Since prostate cancer is a terminal disease with a relatively long time for disease progression, the quality of a patient's life becomes even more critical. Especially in cancer treatment, where the therapy can often feel worse than the disease, the benefits that ABT-627 will bring, coupled with its benign side-effect profile, will have a significant impact on prostate cancer patients' lives.

Clinical Studies

Phase II trials have been completed and the data are being analyzed. Preliminary results for the primary endpoint of time-to-disease progression and the secondary endpoint of time-to-PSA progression show that ABT-627 favorably delays both phenomena with a benign adverse event profile. The results are summarized below:

Disease Progression: The delay in median time-to-disease progression for evaluable subjects was improved by 52% and 43% for the 10mg and 2.5mg doses respectively over the placebo time-to-disease progression of 4.3 months.

Time-to-PSA Increase: A 150% and 150% improvement in median time-to-PSA progression for evaluable subjects was observed for the 10mg and 2.5mg doses respectively over the time-to-PSA progression placebo of 2 months.

Significant dose related decreases were observed in markers of metastatic bone disease.

Key Prostate Cancer Competitors

Product	Company	Phase	Projected NDA Filing	Description	Anticipated Impact on ABT-627
AG 3540	Agouron	III	2000	MMPI	In combination with mitoxantrone/prednisone. Unknown impact.
Marimastat	British Biotech	II	2001	MMPI	Side-effect profile significantly worse than ABT-627. Probably minimal impact.
SU 101	Sugen	III	2002	PDGF TK antagonist	Phase III in combination with mitoxantrone set to start in 1999. Uncertain impact.
AR 623	Aronex	II	2002	All-transretinoic acid	IV liposomal form of ATRA. HRPCCa trial began November 1998. Probably additive.
MGI 114	MGI Pharma	II	2002	Alkylating agent	Lead compound in acylfulvenes. Fairly toxic. Probably additive.
Liposomal Encapsulated doxorubicin	NeoPharm and P&U/Alza and others	II	2002	Anthracycline	Various forms being developed by various companies. Probably additive.
Sataraplatin	BMS	III	2000	Platinum complex	Oral platinum analog w/toxicities comparable to carboplatin. Probably additive.
Taxol	BMS	II	2001	taxane	In various combinations with other chemo agents. Probably additive.
Taxotere	RPR	II	2001	taxane	In various combinations with other chemo agents. Probably additive.

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ABT-594

Descriptive Memorandum

February 2001

Abbott Laboratories

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JH 008165

ABT-594 Opportunity Overview

ABT-594 is a non-opioid, non-NSAID analgesic that is a potent and selective neuronal nicotinic receptor (NNR) agonist being studied for the treatment of pain. ABT-594 is 30 to 100-fold more potent and equally efficacious to morphine in several well-characterized animal models of pain. The preclinical side effect and dependency liability profile of ABT-594 is superior to that of morphine.

ABT-594 is orally administered, and BID dosing is expected. Its initial targeted indication is symptomatic treatment of diabetic neuropathic pain. It is covered by a composition of matter patent through June of 2016, and also has a use patent pending in analgesia that would provide protection through September of 2017.

The IND filing of ABT-594 was in December 1998. A Phase IIb (dose ranging) trial began April 2000 in diabetic neuropathic pain. A Go/No Go decision for clinical efficacy is expected June 2001. The NDA filing is expected in 3Q2003. Development of additional formulations is under consideration (parenteral, transdermal, extended-release).

U.S. sales in 1999 for the key neuropathic pain treatments, Neurontin, carbamazepine, and tricyclic antidepressants (TCAs), are estimated to be \$350 million. Neurontin sales account for the bulk of this, with an estimated 40% of this antiepileptic drug's sales being for neuropathic pain. Neurontin's 2000 sales are expected to reach \$1 billion with perhaps 50% of its use in neuropathic pain. This dollar market value likely underestimates this market's potential due to a number of factors. Only the anticonvulsant, Tegretol (carbamazepine), currently off patent, and Lidoderm, a lidocaine patch, have specific indications for a type of neuropathic pain (trigeminal neuralgia and post-herpetic neuralgia, respectively) in the U.S. Currently, there is an unmet market need for novel neuropathic pain treatments such as ABT-594. Therefore, this compound is likely to be well received in this arena. Outside the U.S., Neurontin recently received an indication in the U.K. for the treatment of neuropathic pain. Despite these opportunities, there has been little to no funding from the pharmaceutical industry to improve diagnosis and treatment of neuropathic pain and drive market growth.

Ex-U.S. sales of carbamazepine and Neurontin for treatment of neuropathic pain are estimated to be approximately \$140MM in 1999. Carbamazepine is still the treatment of choice ex-U.S., with estimated sales of approximately \$90MM in neuropathic pain. Neurontin has achieved only \$53MM in sales for this pain segment, with a price approximately 3-4 times that of carbamazepine, suggesting a patient share of only 10-20%.

Nociceptive pain is categorized by duration (acute or chronic) and by severity (mild, moderate, and severe). The mild and, to a lesser extent, moderate segments have multiple product entries and are generally well satisfied by OTC products such as aspirin, acetaminophen and ibuprofen. The prescription market for nociceptive pain is made up of four key classes of analgesics: NSAIDs, COX-2s, Opioids (and combination products), and Other Non-Opioids. In 1999, sales for these four classes of analgesics exceeded \$12BB (\$6.7BB U.S., \$5.6BB Ex-U.S.)

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Market Size / Prevalence

Pain is the most common symptom of disease and the most frequent complaint with which patients present to physicians. Chronic pain, including both neuropathic and nociceptive pain, is considered to be the single most common cause of suffering and disability in the industrialized world with an estimated 25-30% of the population experiencing some form of chronic pain.

Neuropathic pain is a frequent sequela of diabetes, cancer, AIDS and other viral infections, as well as entrapment neuropathies such as carpal tunnel syndrome. Diabetes and its associated complications are increasing at an alarming rate in the United States. Despite advances in treatment, the development of diabetic complications such as neuropathy remains significant. The diagnosed prevalence of diabetic neuropathy is estimated to be about 2 to 3 million patients, with at least 10 to 20% of those patients experiencing painful symptoms (~200,000 to 600,000.) AIDS-related neuropathic pain is estimated to affect approximately 40% of HIV-infected individuals (~14 million.) Post-herpetic neuralgia (PHN) is another virally induced neuropathic pain syndrome. Annually, acute herpes zoster infection (shingles) occurs in almost a quarter of a million people over the age of 60 in the U.S. alone. Pain lasting more than one year has been reported in 22% of patients over the age of 55 and in 48% of those over 70 years of age. In cancer, nerves can be damaged by mechanical distortion from a tumor mass, infiltration by tumor, chemotherapy, or radiation therapy and, therefore, neuropathic pain is common. An estimate of the prevalence rate for cancer-related neuropathic pain in the U.S. is 200,000 people.

Chronic nociceptive pain categories include osteoarthritis (OA), chronic back and neck pain, rheumatoid arthritis (RA), and cancer pain. These diagnoses are expected to become more prevalent as the population ages. Current overall prevalence for these disorders is staggering (over 200 million worldwide) and, although the diagnosed and treated populations are lower, improved treatment options and awareness have the potential to drive significant growth. OA is one of the most common nociceptive pain conditions treated by primary care physicians and three-fourths of OA sufferers surveyed indicate that the disease interferes with their daily activities. Chronic back and neck pain are also highly prevalent and represent an estimated 40% of a primary care physician's (PCP's) chronic pain patient population.

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Competition, Current Marketed Products:

The following tables show the factored U.S. and ex-U.S. prescription and sales volume for key neuropathic pain therapies in 1999.

1999 Key Neuropathic Pain Products, Estimated TRxs				
Product/Class	1999 U.S. TRx (MM)	U.S. TRx CAGR '97-'99	1999 ex-U.S. TRx (MM)	ex-U.S. TRx CAGR '97-'99
Neurontin	3.3	26.3%	N/A	N/A
carbamazepine	1.0	12.6%	N/A	N/A
TCAs	8.2	1.1%	N/A	N/A
TOTAL	12.5	5.6%	N/A	N/A
Source: IMS, factored for neuropathic uses.				
N/A = not available				

1999 Key Neuropathic Pain Products, Estimated \$ Sales				
Product/Class	1999 U.S. Sales (\$MM)	U.S. Sales CAGR '97-'99	1999 ex-U.S. Sales (\$MM)	ex-U.S. Sales CAGR '97-'99
Neurontin	\$308	28.7%	\$53	57.6%
carbamazepine	\$17	13.1%	\$87	2.5%
TCAs	\$26	-3.3%	N/A	N/A
TOTAL	\$351	21.7%	\$140	10.1%
Source: IMS, factored for neuropathic uses; Ex-U.S. data includes retail pharmacy data from all audited markets				
N/A = not available				

Competition, Products in Development

Almost 100 compounds are currently in development for prescription pain management, though some of these compounds are also being developed for non-analgesic indications. Most of the analgesic compounds in the pipeline represent incremental improvements over the opioids or NSAIDs, or consist of new formulations or delivery mechanisms for the standard analgesics. Fewer than 30% of the compounds in development have novel mechanisms of action. Drugs with novel mechanisms are expected to provide the bulk of promoted competition for ABT-594.

In addition to the novel analgesics in the table below, a number of new formulation and combination products, most often containing an opioid, are in development. Second generation COX-2s are also in development but are not likely to represent major breakthroughs on the scale of the first generation products.

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Analgesia Development Pipeline – Key Novel Agents				
Product	Company	Mechanism	Phase	Comments
pregabalin	Pfizer	Unknown; possibly through (2 nd) subunit binding	III	Neuropathic pain; chronic pain, follow-up to Neurontin
saredutant	Sanofi	NK-2 receptor antagonist	II	General pain; MOA losing favor; active program
ZD4952, ZD 6416	Zeneca	Prostaglandin receptor antagonist	II	Moderate to severe pain, neurogenic pain
GV196771	Glaxo	Glycine antagonist	II	Chronic pain; showing promise
Tepoxalin	Johnson & Johnson	COX/5-LO inhibitor	II	OA, described as 'steroid replacing anti-inflammatory drug'
darbufelone	Parke-Davis	COX/5-LO inhibitor	II	General pain
117mSn DTPA	Brookhaven National Lab/Diatide	Unknown	II	Cancer pain Bone cancer (preclinical)
cizolirtine	Esteve	Substance P agonist	II	Analgesia, antipyretic
ADD 234037/ harkoseride	Houston University	Glycine NMDA associated antagonist	II	Neurogenic pain
LY303870/ lanepitant	Eli Lilly	Neurokinin 1 antagonist	II	Pain (migraine – discontinued)
colykade devacade	Merck	Cholecystokinin B antagonists	II	Pain (UK)
RPR 100893 dapitant	Aventis	Neurokinin 1 antagonist	II	Pain (France)
prosaptide TX14A	Myelos Neurosciences	Unknown	I/II	Diabetic neuropathies, Pain
CNS 5161	Cambridge NeuroScience	Glutamate antagonist, NMDA receptor antagonist	I	Neurogenic pain
HCT-3012	NicOx	Nitric oxide NSAID	I	Pain and inflammation
Sources: ADIS, IMS, Decision Resources, company reports				

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Analgesia Development Pipeline – Nicotinic Mechanisms			
Product	Company	Phase	Comments
GTS-21	Taisho	II	Target is Alzheimer's disease; may have preclinical pain program; looking for partner
CMI 980	Cytomed	Preclinical	Target is pain; epibatidine analog
SIB-T1887	Sibia	Preclinical	Target is pain
FID 072021	Fidia	Preclinical	Target is pain; not actively funding
Sources: ADIS, IMS, company reports			

Unmet Needs

In general, a significant unmet need exists for safer, non-abusable, non-addicting, non-tolerance-producing, and non-scheduled efficacious oral and parenteral analgesic products for the treatment of moderate to severe neuropathic and chronic nociceptive pain.

Unmet Market Needs and the Impact of the Pipeline	
Unmet Need	Pipeline Impact
Efficacy in moderate to severe pain without tolerance, dependence or abuse potential	Novel nicotinic agents like ABT-594 may provide efficacy in more severe pain states without opioid-like liabilities.
Efficacy in neuropathic pain	Pregabalin may provide incremental improvement in neuropathic pain efficacy over gabapentin, but may also have increased frequency of adverse events. Novel nicotinic agents like ABT-594 appear to have efficacy in neuropathic pain, based on animal models.
Reduction in the GI bleeding risk of NSAIDs	COX-2 inhibitors appear to reduce the incidence and severity of GI ulcers and bleeding; second generation COX-2s may increase therapeutic window further; ABT-594 may need to demonstrate low G.I. complication rate.
Overcome ceiling effect of NSAIDs	Preclinical studies did not indicate a ceiling effect for novel nicotinic agents like ABT-594.
Extended dosage intervals or novel delivery mechanisms for improved compliance and convenience	Once weekly dosing formulations being explored for COX-2s, etc. Transdermal patch technology improvements likely; may need to provide line-extension / alternate formulations for ABT-594.
Therapies aimed at disease modification, prevention	Agents that decrease rate of diabetic complications (e.g., aldose reductase inhibitors) or directly treat neuropathy (bimocromol) may decrease incidence of neuropathic pain; thereby decreasing available market for ABT-594.

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Product / Development Background

Scientific Rationale for ABT-594

Recent findings in the understanding of pain mechanisms have led to new conceptual approaches to clinical pain and a new understanding of potential novel molecular targets for analgesic drug development. Molecular targets have included modulators of glutamate neurotransmission (NMDA antagonists), ion channel modulators (neuron specific calcium channels, TTX-resistant sodium channels), neurokinin antagonists (NK-1), and novel anti-epileptics targeting the calcium receptor. None of these approaches has yet produced compounds exhibiting broad-spectrum analgesic efficacy with decreased side effect liability.

ABT-594 is a non-opioid, non-NSAID analgesic that is 30- to 100-fold more potent and equally efficacious to morphine in treating moderate to severe pain in several well-characterized animal models of pain. The preclinical side effect and dependence liability profile of ABT-594 is superior to that of morphine. Mechanistically, ABT-594 is a potent and selective neuronal nicotinic receptor (NNR) agonist with high oral bioavailability in rat, dog, and monkey.

In pre-clinical studies, ABT-594 rapidly distributes to the brain following systemic administration and, like morphine, can work at multiple levels in the central and peripheral nervous system to modulate pain perception. ABT-594 produces antinociceptive effects by interacting at both central and peripheral nAChRs. Injections of ABT-594 into brain at doses 1000-fold lower than given peripherally produce marked antinociceptive activity, indicating that ABT-594 can also activate descending pathways from the CNS to modulate pain processing. It also inhibits the release of the primary nociceptive transmitters, substance P and calcitonin gene related peptide (CGRP) *in vitro*, at the level of the dorsal horn of the spinal cord suggesting that ABT-594 can attenuate mechanisms leading to neurogenic inflammation, central sensitization and consolidation of pain-mediated neuronal changes.

ABT-594 is expected to be a highly differentiated product. It is expected to be the first neuronal nicotinic receptor agonist to receive an indication for pain. It has a novel mechanism of action and a potentially broad coverage of chronic pain conditions. In addition, it has an opioid-like efficacy without tolerance, dependence or abuse potential, while having equivalent/superior efficacy to other drugs used to treat neuropathic pain.

Clinical Studies

Human clinical trials began in 1997. Phase I trials with an oral solution formulation indicated that 150ug/day would be the maximum tolerated dose. Results from subsequent phase I and phase II trials with soft elastic capsule (SEC) and hard gelatin capsule (HGC) suggest that higher doses would be tolerated. Phase IIa studies with ABT-594 SEC formulation suggest a trend towards analgesic effect at 75ug BID, the maximum dose studied in this protocol. ABT-594 was generally well tolerated in these studies. The most common adverse events for subjects receiving ABT-594 75ug BID were nausea (15%), headache (13%), dizziness (7%), insomnia (6%), and vomiting (5%).

A phase IIb study for neuropathic pain at higher, titrated doses of ABT-594 began in April 2000 and ends in June 2001. A total of 320 patients is anticipated to be included in the study.

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Considerations**Target Profile:**

The current status of ABT-594's profile vs. target profile is summarized in the table below:

Target Profile Attribute	Probability
Not scheduled (DEA)	High
Very few abnormal Liver Function Tests	High
Few Drug Interactions	High
BID / TID dosing	High
No reduced efficacy or increased AEs in nicotine users	High
Onset of action 1.5 – 2.0 hours	High
Neuropathic efficacy	Medium
No tolerance, dependence or withdrawal	Medium
Other safety OK	Medium
No cravings in ex-nicotine users	Medium
Low nausea / vomiting	Low

Label Strategy:

BASE: Indicated for the treatment of diabetic neuropathic pain.

- UPSIDE:
- 1) Treatment of pain associated with OA
 - 2) Treatment of post-herpetic neuralgia
 - 3) Treatment of neuropathic pain
 - 4) Treatment of chronic pain
 - 5) Treatment of cancer pain

Cost of Goods Sold:

The projected average daily dose is expected to be a maximum of approximately 600 mcg base equivalent / day. Based upon this dosage projection and the estimated cost of bulk drug substance of \$40M per Kg base equivalent, the estimated cost for drug substance at launch will be approximately \$0.024 per day.

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Pricing.

US: Pricing new, and particularly novel, products at a reasonable premium will likely continue to be the norm in the years leading up to the launch of ABT-594. Current forecast assumptions put the price of ABT-594 at a level comparable to Celebrex and Neurontin, grown at a modest 2% per year to launch year AWP of approximately \$95 for a 30 day prescription.

Ex-US: New pain medications must demonstrate a true advantage in efficacy and/or side effects to receive regulatory approval, especially by the European Medicines Evaluation Agency (EMA); assuming the target efficacy and tolerability profile of ABT-594 is achieved, ABT-594 would meet this requirement. Because ABT-594 may have application in both neuropathic and chronic nociceptive pain, the ex-U.S. pricing assumption for ABT-594 is comparable to COX-2 pricing. The current average price for COX-2's is approximately \$1.10 per day; however, this reflects a large percentage of sales in "free-pricing" countries, where COX-2s launched first, which tend to have higher than average prices. Therefore, the average ex-U.S. price for ABT-594 is assumed to be \$0.90/day.

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ABT - 751

Descriptive Memorandum

February 2001

Abbott Laboratories

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ABT-751

Opportunity Overview

Cytotoxic agents and hormones constitute the dominant classes of drugs available to treat cancer and are responsible for 96% of the total market. Since 1993, Taxol, a taxane developed and marketed by BMS, has been widely used. Another taxane, Taxotere, developed and marketed by Aventis, was launched in 1996. Combined worldwide sales of these two products were of nearly \$2 Billion US in 1999. Clinically, the development of drug resistance is the primary factor that limits the efficacy achievable with these drugs.

Abbott's anti-mitotic agent (ABT-751) is a novel, oral cytotoxic agent that acts by a mechanism similar to that of the taxanes but retains activity against taxane resistant cells. ABT-751 binds to the colchicine site on tubulin and inhibits the *in vitro* polymerization of microtubules. The interference with normal microtubule dynamics leads to a block in the cell cycle at the G2/M phase that ultimately results in the induction of cellular apoptosis. ABT-751 is a potent antimitotic agent that inhibits the proliferation of a broad spectrum of human tumor derived cell lines including those that are paclitaxel and doxorubicin resistant due to the multidrug-resistant (MDR) phenotype or other genetic changes.

ABT-751 demonstrated impressive oral antitumor activity when evaluated in both syngeneic and human xenograft tumor models. The antitumor response was independent of the MDR status of the model, consistent with the activity observed in cell cultures. In sharp contrast with other cytotoxic drugs, the maximum tolerated dosage of ABT-751, on a q.d. 1-5 schedule, could be administered for an extended period (q.d. 1-21 or q.d. 1-28) resulting in a dramatic enhancement of the antitumor activity. These results suggest that the colchicine site ligands, such as ABT-751, will exhibit a broad spectrum of activity that will be distinct from that of other classes of antimitotic drugs. Oral availability of the compound is high. Taxol and Taxotere, in contrast, have no oral bioavailability.

The most significant finding in toxicology studies was a change in systemic and pulmonary vascular resistance following intravenous infusion of ABT-751 to anesthetized dogs. These effects led to an inverse response in cardiac output. Similar changes were observed following infusion of a structurally unrelated colchicine-site ligand, and therefore most likely represent a class effect. Additional toxicology studies focusing on vascular pathology will be performed to further elucidate this finding.

ABT-751 was administered to patients with advanced cancer in Japan in a Phase I study. Toxicities seen after single doses and 5 days of q.d. dosing were nausea, vomiting, diarrhea, epigastric pain, ileus and peripheral neuropathy. Grade 2 toxicity was peripheral neuropathy and associated paresthesias. Pharmacokinetic analyses showed plasma concentrations equivalent to those that affected systemic resistance and cardiac output in the anesthetized dog study. However, no adverse cardiovascular effects were observed in the Japanese Phase I trial. Evidence of ABT-751 efficacy was exhibited in one patient with uterine sarcoma, one patient with NSCLC after single doses, one patient with gastric cancer and one patient with uterine cervical carcinoma demonstrated decreased tumor markers after repeated dosing.

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The planned initial Phase I study in the U.S. will determine the maximum tolerated dose and dose-limiting toxicities of ABT-751 given orally once a day or twice daily for multiple cycles in patients with advanced malignancies. In addition, pharmacokinetics in a western population, and optimal dose and schedule will be determined. Phase II studies will be initiated in patients with different cancer types:

- Refractory breast (taxane failures)
- Hormone refractory prostate
- Bladder
- Lung
- Cervical
- Hepatocellular
- Other possibilities: colorectal, sarcoma, renal cell, pancreatic, HNSCC

Cytotoxic agents represent the largest, and fastest growing, class of oncology agents by sales volume. The following chart summarizes the value of the current oncology market

Global Sales by Market Segment (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est)	CAGR '96-'98
Hormone	4,414	4,784	4,884	5,000	5.2%
Cytotoxic	4,278	5,212	6,268	7,300	21.0%
Adjunctive	3,367	3,651	4,166	4,900	11.2%
Total	12,059	13,647	15,318	17,200	12.7%

Source: Datamonitor

Sales by Region (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est)	CAGR '96-'98
US	5,564	6,276	7,422	8,500	15.5%
Ex- US	6,495	7,370	7,896	8,700	10.3%

Source: Datamonitor

This growth of the cytotoxic segment has been driven primarily by the introduction of new, more effective and expensive therapies such as Taxol (paclitaxel/BMS), Gemzar (gemcitabine/Lilly), Taxotere (docetaxel/RPR) and Hycamtin (topotecan/SB). Uptake of these newer agents, however, can be dependent on the cost sensitivity of the local market.

The clinical targets identified for this compound include late stage breast cancer, late stage NSCL cancer (on-label), with late stage ovarian and pancreatic cancer as additional cancer types where efficacy has been demonstrated, but not filed. This product may also be potentially efficacious in cancers such as gastric, colorectal, prostate, bladder, esophageal, hepatocellular (ex US), lymphoma, and leukemia. Targets will be refined as we know more about this compound's in-vivo activity.

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The following tables summarize the key competitive products by indication (US data only):

Late Stage Breast	
Product	Share
Cyclophosphamide/Cytoxan/BMS	18.7
Doxorubicin/Adriamycin/P&U	17.11
Docetaxel/Taxotere/RPR	16.25
Paclitaxel/Taxol/BMS	16.11
Trastuzumab/Herceptin/Genetech	11.26

Late Stage NSCL	
Product	Share
Carboplatin/Paraplatin/BMS	50.32
Paclitaxel/Taxol/BMS	44.14
Vinorelbine/Navelbine/Glaxo	22.78
Gemcitabine/Gemzar/Lilly	22.14
Cisplatin/Platinol/BMS	11.28

Late Stage Ovarian	
Product	Share
Paclitaxel/Taxol/BMS	47.11
Carboplatin/Paraplatin/BMS	45.42
Topotecan/Hycamtin/SKB	22.54
Dox SL/Doxil/Alza	9.14
Cisplatin/Platinol/BMS	7.58

Late Stage Pancreas	
Product	Share
Gemcitabine/Gemzar/Lilly	78.5
5-FU/Eludex/ICN Pharma	21.0
Leucovorin/	10.7
Cisplatin/Platinol/BMS	4.72

Compounds in Development

ABT-751 induces a mitotic block by binding to the colchicine site on tubulin and thereby affecting tubulin polymerization. There are no currently available drugs which function by the mechanism described above. However, vinca alkaloids and taxanes fall into the broad category of anti-mitotics although they produce the anti-mitotic effect through different mechanisms. The following table summarizes anti-mitotic compounds in development.

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Company	Compound	Indication	Status of compound	Status of subject
Colchicine-site ligands				
Oxigene	combretastatin-A4 phosphate	Tumor vasculature	Phase I	active
Tularik	T138607 (phosphate prodrug)	Cancer (unspecified)	Phase I	active
Tularik	T900607	Cancer (unspecified)	Preclinical	active
ICI/CRC	Amphethinile	Cancer (unspecified)	Phase I (abandoned 1988)	inactive
Wellcome Research	1069C	Cancer (unspecified)	Phase I (abandoned 1996)	inactive
NIH	Trimethylcolchicinic acid	Various tumors	Phase I (1990, abandoned)	inactive
Parke-Davis	CI-980	ovarian, colorectal	Phase II (abandoned 2000)	inactive
Vinca alkaloid-site ligands				
BASF	LU103793 (dolastatin 15 analog)	Cancer (unspecified)	Phase II (abandoned)	active
Servier	Vinxaltine	Cancer (unspecified)	Phase I	unknown
NCI	dolastatin 10	Adv. Cancers	Phase I	unknown
Teikoku Hormone	TZT-1027 (dolastatin 10 analog)	Cancer (unspecified)	Phase I (Jpn)	unknown
Lilly	LY 355703 (cryptophycin 52)	Cancer (unspecified)	Preclinical	unknown
Takeda	Maitansine	Cancer (unspecified)	Preclinical	unknown
Microtubule stabilizing agents (non-taxanes)				
Soc. Biotech. Res/ Bristol-Myers Squibb	Epothilone	Cancer (unspecified)	Preclinical	active
Bristol-Myers Squibb	eleutherobin	Cancer (unspecified)	Preclinical	active
Pharmacia & Upjohn	sarcodictyins	Cancer (unspecified)	Preclinical	active
Takeda	GS-164	Cancer (unspecified)	Preclinical	active

The novelty of this mechanism offers the promise of differentiation that will diminish the threat from potential competitors. However, this novelty is balanced by the similarity to current mechanisms, such as taxanes and vinca alkaloids, which suggests the promise of clinical efficacy. With the opportunity to be first or second to market with an agent that binds to the colchicine site, the competitive situation seems modest.

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ABT – 492

Descriptive Memorandum

February 2001

Abbott Laboratories

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JH 008179**

Hancock_AB 492

ABT 492**Overview**

The commercial success of fluoroquinolones such as ciprofloxacin and levofloxacin, along with the desire to further improve the properties of these compounds (microbiological spectrum and safety, for example) has led to fierce competition to identify analogs with superior therapeutic properties. In addition, the development of resistance to present antibiotics will drive a continued need for new agents. Goals for a quinolone antibiotic include broad-spectrum indications equal to trovafloxacin, antibacterial activity comparable to trovafloxacin, tolerability comparable to levofloxacin, oral and intravenous formulations, once daily dosing, length of treatment equal to moxifloxacin, and an acceptable cost of goods. ABT-492, an in-licensed compound from the Wakunaga Pharmaceutical Co., is being developed for evaluation to meet these goals:

The *in vitro* antibacterial activity of ABT-492 was consistently more potent than trovafloxacin against most quinolone-susceptible pathogens, including species responsible for community and nosocomial respiratory tract infections, urinary tract infections, blood stream infections, skin and skin structure infections, and anaerobic infections. The compound has potent activity against multidrug-resistant *S. pneumoniae* (penicillin-, macrolide-, tetracycline-resistant) and retained activity against *S. pneumoniae* strains resistant to other quinolones including trovafloxacin. ABT-492 was also highly active against anaerobes and ciprofloxacin-susceptible *P. aeruginosa*. ABT-492 was as active as trovafloxacin against *C. trachomatis*, indicating good intracellular penetration. Thus, ABT-492 is likely to be a useful broad-spectrum antibacterial agent. The enhanced antibacterial activity of ABT-492 relative to ciprofloxacin, levofloxacin, and trovafloxacin is likely to be explained, in part, by its potent interactions with bacterial topoisomerases. ABT-492's equivalent activity against both the DNA gyrase and the topoisomerase IV of pathogens, give ABT-492 a potential for decreased development of resistance.

The *in vitro* potency data suggests that ABT-492 has the potential to be therapeutically effective at doses comparable to trovafloxacin and superior to levofloxacin. In addition, ABT-492 was consistently more potent than trovafloxacin against MRSA and vancomycin-resistant enterococci. In both these cases, however, therapeutic utility remains to be assessed in the clinical setting.

S. pneumoniae was chosen as the dose-defining pathogen since it is the key pathogen in severe respiratory tract infections and treatment of infections caused by this pathogen has traditionally been a weakness of most quinolones. For treatment of fluoroquinolone-susceptible *S. pneumoniae* respiratory tract infections, oral dosing may be similar to trovafloxacin based on data generated in lung infection models. Because of the excellent potency of ABT-492 against fluoroquinolone-resistant *S. pneumoniae* with an MIC₉₀ of 0.12 µg/ml, this group of emerging strains may be targeted as a key differentiation point from other quinolones. Also, data from the thigh infection model suggests significantly greater efficacy for ABT-492 than for trovafloxacin.

The Market

ABT-492 is broad-spectrum anti-infective agent with potential application across a broad range of indications, including respiratory infections, genito-urinary infections, and skin/soft tissue infections. It is assumed that a pediatric formulation would not be a part of the primary development plan due to the known adverse events caused by quinolones in pediatric populations. Nonetheless, reports of quinolone pediatric development has been reported (gatifloxacin), hence the pediatric market should be regarded as a potential upside for this quinolone should its safety profile merit its use in pediatrics.

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Current Treatment Options

Class	Mechanism of Action	Comments
Penicillins	Cell wall synthesis inhibitor	Mostly generic, class has seen significant decrease as a result of penicillin resistance.
Cephalosporins	Cell wall synthesis inhibitor	Some generic, class has seen significant decrease in use as a result of prevalence of β -lactamase producing strains and modification of penicillin-binding proteins.
Tetracyclines	Protein synthesis inhibitor	Generic agents, relatively high levels of resistance but are still useful in some indications.
Sulfonamides	Folic acid synthesis	Generic agents, relatively high levels of resistance but are still useful in some indications.
Macrolides	Protein synthesis inhibitor	Widespread use in RTI, macrolide resistance has been increasing rapidly, but has not yet translated into declines in clinical efficacy; <i>H. flu</i> activity continues to be class weakness, along with GI adverse events, drug-drug interactions, & taste perversion.
Quinolones	DNA synthesis inhibitor	Fastest growing antibiotic class, used in a broad spectrum of indications; class historically associated with poor Gram+ pathogen coverage and sub-optimal safety profiles; newer agents (Levaquin, Tequin, Avelox) have improved dramatically along both spectrum and safety dimensions.
Oxazolidinones	Protein synthesis inhibitor	Newest antibiotic class to reach market, due to limited Gram- profile will be used primarily in nosocomial setting.

U.S. Market

1999 U.S. antibiotic prescription and sales data are presented in the table below.

U.S.	TRXs (MM)		1995	1996	1997	1998	1999	CAGR ₉₅₋₉₉
	TRXs (MM)	Tab/Cap	220	215	211	208	221	0.1%
		Oral Susp.	76	66	63	59	61	-5.3%
		I.V.	NA	NA	NA	NA	NA	NA
	Sales (\$MM)	Tab/Cap	\$4,057	\$4,220	\$4,467	\$4,848	\$5,715	8.9%
		Oral Susp.	\$1,075	\$979	\$977	\$1,001	\$1,120	1.0%
		I.V.	\$1,865	\$1,829	\$1,855	\$1,890	\$2,117	3.2%

Tab/cap and oral suspension prescriptions had been declining 1-2% per year in the period of 1995-1998, presumably from increased attention to appropriate prescribing in the face of increasing resistance; however, prescriptions recovered in 1999, though this may be explained at least in part by a relatively late 1998-99 flu season. Even in the face of this negative pressure on antibiotic use, however, sales in the U.S. have continued to increase, particularly in the tab/cap market. This is due to the trend of replacing relatively low-cost generic agents with higher priced premium antibiotics; during 1995-1999, generic tab/cap prescriptions declined by 30MM. So while negative pressure on the use of these antibiotics continues, it appears the market is willing to bear higher costs for agents that meet unmet need. The IV market has grown slightly in terms of sales, also being driven largely by the replacement of generic agents with more costly branded agents.

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Leonard Deposition Exhibit 1

P's Exhibit 32

Part 3

Quinolones have seen dramatic growth, with oral and IV sales growing at 17% and 16% compound annual rates, respectively, from 1995-1999. This growth is a function of the newer quinolones successfully penetrating the RTI segment, which was initiated with the 1997 launches of Levaquin and Trovan (withdrawn) and continues with the recent introductions of Tequin and Avelox.

Ex-U.S. Market

Ex-U.S. sales of antibiotics totaled \$11.7 billion in 1999. The tab/cap represents the largest segment, with sales of \$9.4 billion on 770 MM TRX. TRX growth has been flat, with a 1996-99 CAGR of 0.5%; the use of antibiotics is predicted to slowly decline due to more judicious use of antibacterials in the face of increasing bacterial resistance.

Ex-US, the quinolone class accounted for 8% (62MM) of total tab/cap market prescriptions and 13% of sales (\$1.2 billion). Ciprofloxacin is the market leader ex-US, with approximately 47% of the quinolone market Rx's (29MM) and 44% (\$530MM) of sales. Levofloxacin launched in many European markets in 1998/1999 and holds approximately 14% Rx share of the European quinolone market, and 0.8% of the overall tab/cap market. Although grepafloxacin and trovafloxacin also launched in some European countries in 1999, both products were recently pulled from the market due to liver toxicity and other complications. Moxifloxacin launched in Germany in Q4 1999, but has not yet been approved in other markets. In Japan, levofloxacin launched in 1994 and still commands a 65% Rx share of the quinolone market and 10% of the Japanese tab/cap market overall. Japan accounts for approximately 80% of ex-US levofloxacin sales (\$370MM).

1999 Ex-US Tab/Cap Market						
Class	Sales (\$MM)	Sales Share	Sales CAGR '96-'99	TRXs (MM)	TRX Share	TRX CAGR '96-'99
Market	\$9,348	-	3.6%	770	-	0.8%
Quinolone Class	\$1219	13%	-12%	62	8%	NA
Cipro	\$530	5.7%	4.9%	29	3.8%	NA
Levaquin	\$466	5.0%	NA	18	2.3%	NA
Trovan	\$12	0.1%	NA	0.5	0.1%	NA

Competition

The anti-infective pipeline is very competitive, but most of the competition is focused on improving the activity and safety of the quinolones. Ketolide development is the only other area of activity which is in late stage of development. The quinolone compounds in present development may fall out because of safety or lack of activity against resistant pathogens.

Competitive Analysis - Emerging Competition					
Product	Company	Class	Phase/Estimate d Time to Market	Country	Comment
Ketek (telithromycin)	Aventis	Ketolide	Filed 3/00 Est. launch 3/01	U.S.	Respiratory indications; filed NDA 3/00; 800 mg QD; first in ketolide class to reach market.

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Competitive Analysis - Emerging Competition					
Product	Company	Class	Phase/Estimated Time to Market	Country	Comment
Factive (gemifloxacin)	SKB	Quinolone	Filed 12/99 Est. launch 12/00	US	Superior to quinolones for MRSA; highly potent vs. RTI pathogens <i>H. flu.</i> , <i>M. cat.</i> , and <i>S. pneumo</i> and UTI pathogens <i>E. coli</i> and <i>P. mirabilis</i> , CRSP; potency > spart, trov, gropa and \geq mox; activity vs. <i>P. aeruginosa</i> ; good atypical and mycoplasma coverage; intracellular penetration; low photo/CNS tox; 700 patient database
Sitafloxacin	Daiichi Sankyo	Quinolone (IV only)	III II Est. launch 2002	Japan U.S., Europe	Very potent MRSA, pseudomonas and bacteroides activity; diarrhea, ALT, low WBC; will likely be target to severe rather than community infections
Eccenofloxacin	Chief Foods	Quinolone	II Est. launch 2002	UK	Active against UTI and RTI pathogens; superior to lome and oflo vs. <i>P. aeruginosa</i> . $T_{1/2}$ = 14-19 hr; will likely be target to severe rather than community infections
CS-940	Sankyo	Quinolone	II Est. launch 2002	Japan	Active against G+/-; excellent activity against <i>H. flu.</i> , <i>C. jejuni</i> , <i>M. pneumo</i> , and <i>C. trachomatis</i> ; greater potency than cipro; $t_{1/2}$ ~7 hr; BA ~80%
T-3811	Toyama/BMS	Quinolone	I Est. launch 2005	Japan	Excellent potency and low toxicity
DC-756	Daiichi Pharma	Quinolone	Pre-clin Est. launch 2006	Japan	Low toxicity; in vitro potency \geq trov, STFX & HSR-903

Unmet Needs

Overall unmet need in the anti-infective market is low. Resistance represents the largest unmet need, which will continue to evolve over time. Satisfaction with other product attributes, such as convenience, spectrum of activity, and tolerability/safety is quite high. Any improvements in these areas will be incremental and will offer little in the way of differentiation.

ABT-492 is one of the most active agents against the resistant organisms. It has indications that will have a low propensity for the development of resistance. ABT-492 will be developed to maximize any opportunities to shorten therapy. ABT-492 was chosen from hundreds of quinolones because of its potential to be well tolerated and safe in humans. ABT-492 will have few interactions with other drugs.

Unmet Need	Pipeline Impact
Activity against resistant organisms	<i>Strep. pneumo</i> , MRSA, and VRE represent most problematic pathogens although new quinolones/ketolides do well with most resistant <i>Strep. pneumo</i> strains; quinolone-resistant <i>Strep. pneumo</i> may develop; pseudomonas resistance is also increasing; resistance will likely continue to be a source of unmet need due to its dynamic nature.
Low propensity for resistance development	Given that most compounds in development are from classes of drugs already in use, this need is largely unmet. Unclear how quickly resistance will build to new classes of drug; gatifloxacin claims 8-methoxy functional group results in lower propensity for resistance development
Convenience (duration/frequency)	Standard moves toward 5-7 days of therapy with QD dosing; may start to see 3-day therapies for some indications (AECB)
Increased tolerability	While some degree of unmet need exists, increasingly, agents (which have not been withdrawn) are reaching the marketplace with adverse event profiles that approach clinical insignificance; a very clean safety

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	profile should be regarded as a necessary component rather than a differentiating one
Few drug-drug interactions	Quinolones, macrolides, and ketolides all interact with other drugs to varying degrees; a potent drug with no interactions would be a benefit in this market

Considerations

Product Usage: Physicians are likely to use ABT-492 for the sicker patients with the most difficult infections to treat. In the outpatient arena it will be used to treat community-acquired pneumonia and acute bacterial exacerbations of chronic bronchitis in the older patients with an underlying illness. It will also be used in the hospital for the community-acquired pneumonia patient who requires hospitalization and for serious nosocomial infections.

While many regard quinolones as agents that should be reserved for 2nd line use, their activity against *H. influenzae* and resistant *Strep. pneumoniae* (which current macrolides do not offer) have resulted in a high level of acceptance for empiric 1st line use. The improved safety profiles of several recent quinolones have facilitated their use as 1st line agents. Provided that ABT-492 is proven to have a benign safety/adverse event profile, it will likely receive usage in both 1st-line (non-severe) and 2nd-line (severe) infections.

Side Effects: The quinolone class has potential prolongation of the QT interval and other cardiovascular effects. There is also increased regulatory scrutiny due to recent quinolone withdrawals from international markets. ABT-492 has been evaluated in the standard *in vivo* models used to evaluate QT interval potentials of other antibiotics and has shown no evidence of increasing QT. Also, compared to marketed quinolones, preclinical studies show no evidence or no increase incidence of CNS drug concentration (i.e. less potential for dizziness); phototoxicity; and liver toxicity.

Off-label use: It is difficult to predict at this time what off-label uses will be seen for this compound. Initial development will be for the more common respiratory, urinary tract, skin, and hospital infections. Other indications will be evaluated after the primary approval of this compound. Many of the secondary indications will get usage before we have regulatory approval.

COGS: The initial cost of goods is in \$6000/kg range, but will come down rapidly after the initial starting materials are determined. At time of launch ABT-492 will have a cost of goods in the \$1500/kg range which is competitive compared to other quinolones and other new antibiotics.

Dosing: Based on animal models and the *in vitro* activity of ABT-492 the dose for most oral indications will be in the range of 100 to 200 mg give once daily.

Development/Regulatory: Anti-infective compounds are well understood by regulatory agencies globally and they have clearly defined clinical development path and regulatory guidelines for reference. Abbott Laboratories has been in this arena for many years and has experience with the FDA and European regulatory agencies and so the hurdles to development are well known. ABT-492 has begun but not yet completed its first Phase I study in healthy volunteers.

Other Approaches: Because of the well defined development guidelines there are not many options. The major development options are in dosing regimens. ABT-492 is a very potent drug which has demonstrated rapid killing of pathogens *in vitro* and *in vivo*, and the development plan will attempt to shorten treatment durations to increase the competitive advantages of this activity.

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Pricing: The community infection market is quite competitive from a pricing standpoint, with recent quinolones priced at approximately \$45 per 5-7 days of therapy. The pricing strategy will depend on strengths/weaknesses of the ABT-492 product label, the competitive landscape at launch, and the managed care environment, but current pricing assumption is parity for ABT-492 with respect to other quinolones.

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ABT – 510

Descriptive Memorandum

February 2001

Abbott Laboratories

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ABT 510**Overview**

There is abundant evidence that primary tumor growth and metastatic progression require new blood vessel formation (angiogenesis). Tumors secrete inducer proteins including bFGF and VEGF that activate microvascular endothelial cells (EC) causing them to proliferate, migrate and organize into capillary structures. Activated endothelial cells also enhance malignant progression by producing signal molecules (cytokines) that inhibit programmed cell death (apoptosis) of tumor cells. Since anti-angiogenic therapy targets genetically stable endothelial cells, resistance typically seen following cytotoxic chemotherapy is not observed. Moreover, angiogenesis inhibitors should not have the intrinsic toxicity of anti-proliferative chemotherapy. Angiogenesis is also a feature of several other pathophysiologic states of large unmet medical need (macular degeneration, psoriasis, and arthritis, among others).

Angiogenesis sustains the growth and progression of tumors. Unlike chemotherapy or radiation, both of which can damage normal cells in addition to tumor cells, anti-angiogenic agents are hypothesized to prevent growth of new blood vessels and to disrupt critical tumor survival signals produced by EC. These agents may keep tumors in a dormant state for as long as the compound is administered and tumor regressions may occur. Proof of this principle has been demonstrated in pre-clinical models. Currently, at least thirteen compounds with anti-angiogenic activity in cancer are in various phases of clinical development, however few act directly and specifically on the angiogenesis process. Anti-angiogenesis drugs are not expected to replace or compete with current therapies. Instead, if these agents prove to be effective, it is believed that they will be used as supplemental therapy to prevent metastasis following surgery, cytotoxic chemotherapy or radiotherapy. As for cases where tumors have already metastasized, these agents could slow down disease progression and maintain "disease dormancy".

Thrombospondin-1 (TSP-1) was the first natural angiogenesis inhibitor to be discovered. TSP-1 is a large, multifunctional protein. TSP-1 rapidly inhibits EC migration and increases EC apoptosis through activation of caspase-3-like proteases. The normal tissue expression of TSP-1 limits inappropriate neovascularization, however it is transcriptionally activated by the tumor suppressor gene product p53. Therefore, TSP-1 is down-regulated and under-produced in p53 defective tumors. In rodent models, ectopic overexpression of TSP-1 inhibits the malignant phenotype as does direct administration of TSP-1 in the circulation. However, direct clinical use of TSP-1 is not feasible because of its scarcity, large size and multiple other biological functions.

The angiogenic activity of TSP-1 has been localized to the 50,000 MW N-terminal stalk region of this protein, and more specifically to the properdin (Type-1) repeats within this region. Although small synthetic peptides within this region have only weak antiangiogenic activity, it was discovered that a single D-amino acid replacement in a properdin region peptide led to an increase in activity of greater than 1000-fold. ABT-510 is a parenterally available nonapeptide. Although ABT-510 competes with TSP-1 for binding to the EC, the exact mechanism of anti-angiogenesis is unknown.

ABT 510 is supplied for clinical use as a sterile solution in acetate salt in 5% dextrose. ABT 510 is soluble and stable in water.

In vitro, ABT 510 inhibits chemotactic VEGF/bFGF-stimulated migration of human microvascular endothelial cells (EC) with an IC50 of approximately 0.250 nM. This effect is EC specific. ABT-510 (10mg/kg/day subcutaneously) blocks VEGF-induced corneal vascularization in mice. It potently and selectively competes with TSP-1, binding the CD 36 receptor.

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ABT 510 inhibits tumor progression in vivo. ABT 510 (20mg/kg/day subcutaneous administration) inhibited tumor progression (78% growth inhibition at day 38) in a model of human breast cancer (MDA-MB-435) growing in the breast pads of nude mice. Dose dependent inhibition of B16F10 melanoma lung metastases was observed in a second murine model. ABT 526, a molecule highly similar to ABT 510 (which was not advanced into human trials because of congenital formation) was administered to 23 companion dogs (25mg SQ BID) with sporadic cancers (head and neck carcinoma, lymphoma, sarcoma, etc) refractory to conventional chemotherapy. Surprisingly, 2 complete responses, 5 partial responses ($\geq 50\%$ shrinkage) and 6 cases of disease stabilization were observed.

Assays for toxicity, histamine release, hemolysis, T-cell function neutrophil migration, platelet aggregation, receptor (CERP) screening and CNS function were unremarkable. ABT-510 produced no physiologically significant changes in cardiovascular or hemodynamic function in anesthetized dogs. In addition, there were no physiologically significant changes in clinical blood chemistry profiles or cardiac electrophysiologic function in response to ABT-510. Doses that were many times higher than the predicted efficacious concentration produced a moderate reduction in mean arterial blood pressure in conscious monkeys. ABT-510 was not mutagenic in the Ames assay. It is concluded therefore that ABT-510 has an excellent pre-clinical safety profile.

ABT-510 is currently in Phase I clinical trials. Because of its exceptional safety profile, normal volunteers are being dosed with ABT-510 to establish human safety and pharmacokinetic parameters. Review of these data will lead to a Go/NoGo decision for Phase II trials in the Summer of 2001.

The market

Cytotoxic agents represent the largest, and fastest growing, class of oncology agents by sales volume. The following chart summarizes the value of the current oncology market. The market for products to treat cancer is changing rapidly. It is a growing market fueled by:

- Increasing disease incidence
- New product entries
- New therapeutic paradigms
- A growing adjunctive market, which increases the number of patients eligible for chemotherapy
- Intense research and competition

The increase in the aging population in developed countries increases the incidence of cancer. The diagnosed cancer incidence and prevalence in seven major markets, including the U.S., France, Germany, Italy, Spain, U.K. and Japan are close to 3 million and 10 million respectively. The numbers are increasing steadily. Currently, about one-third of the new medicines in development are targeted against cancer.

Cancer is not a single disease, but includes more than 100 different disorders, which have at their core uncontrolled cell growth. Of these disorders, the cancer types that offer the greatest commercial opportunity include breast, colorectal, lung, ovarian and prostate (based on incidence/prevalence/unmet need). Treatment of breast, lung and prostate cancers account for more than 50 percent of the direct medical costs of cancer therapies. Other cancer types, specific to one or more of the major international markets, may provide niche opportunities. For instance, stomach (gastric) cancer is relatively common in Japan but not in the U.S. or Europe; similarly, liver cancer has a greater occurrence in Japan, Italy and Spain.

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Depending on tumor type, cancer can be treated with surgery, radiation, chemotherapy (cytotoxic), hormonal therapy or a combination of any of these. For the purpose of this analysis, we will define the cancer market as chemotherapeutics and the adjunctive therapies used to counter the effects of chemotherapy and radiation therapy. The following charts summarize the global sales for these products.

Global Sales by Market Segment (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	CAGR '96-'98
Hormone	4,414	4,784	4,884	5.2%
Cytotoxic	4,278	5,212	6,268	21.0%
Adjunctive	3,367	3,651	4,166	11.2%
Total	12,059	13,647	15,318	12.7%

Source: Datamonitor

Sales by Region (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	CAGR '96-'98
US	5,564	6,276	7,422	15.5%
Ex- US	6,495	7,370	7,896	10.3%

Source: Datamonitor

Chemotherapeutic agents

Cytotoxic therapies include classes such as alkylating agents, anti-tumor antibiotics, anti-metabolites and antimitotics (taxanes). These agents are toxic and demonstrate dose-limiting side effects. The commercial value of this segment is significantly understated, as most of the products are available in generic form.

The growth of the cytotoxic segment in the past three years has been driven primarily by the introduction of new, more effective and expensive therapies such as Taxol (paclitaxel/BMS), Gemzar (gemcitabine/Lilly), Taxotere (docetaxel/RPR) and Hycamtin (topotecan/SB). Utilization of these newer agents, however, appears to be dependent on the cost sensitivity of the local market. For example, secondary sources indicate that Taxol has recorded over 60% of its global sales in the US market alone and is prescribed with far less frequency in the more cost sensitive UK, German and French markets.

Most chemotherapeutic agents are indicated for just one or two cancer types, but get significant off-label use once approved. Up to 60% of an oncology product's use is potentially for off-label indications. Much of this use is driven by the publication of data and/or approvals in other countries.

Hormonal therapies

Of the top-selling drugs in each major geographical region, *hormone therapies* contribute approximately one-third of the sales ex-US and one-fourth in the US. Hormone therapies for the treatment of cancer include Lupron (leuprolide/TAP), Zoladex (goserelin/Zeneca), Nolvadex (tamoxifen/Zeneca) and other agents used to treat hormone responsive diseases such as prostate and breast cancer. These agents are generally administered chronically and have reduced side effects compared to cytotoxic therapies. Sales of this category are driven primarily by Lupron and Zoladex. The US market has become increasingly cost sensitive in the Medicare sector, which accounts for over 70% of Lupron sales.

Adjunctive agents

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The availability of effective adjunctive agents also allows the cytotoxic chemotherapeutic agents to be administered at higher doses and/or more frequently, or used in a more palliative role, since the adjunctive therapies can reduce the impact of the chemotherapy on the patient's quality of life. Agents in this class include immunostimulants, anti-emetics and bisphosphonates. The growth of this market is linked to the growth of the cytotoxic market, as the increased use of cytotoxic agents drives an increased use in adjunctive therapy. The highest selling product in this class is Neupogen (filgrastim/Angen) with 1998 sales of over \$1 billion.

Biologic Therapy

New therapies under development offer the promise of fulfilling several unmet needs in the treatment of cancer. Experts have predicted that in the future early therapy for breast cancer will be dominated by biological approaches, such as monoclonal antibodies (Herceptin/Genentech), which is widely thought to have strong market potential. Genentech recently reported strong second quarter sales of the product in the US of \$46.2 million, and it is estimated that if only half of US women with breast cancer who over-express this gene received Herceptin, sales would top \$600 million. In addition to monoclonal antibodies, other biological approaches include vaccines and gene therapy.

Future Trends

Emerging science in the past decade offers the potential to radically alter the paradigm for cancer therapy and presents opportunities for fundamentally new ways of approaching the disease. New therapies offer the promise of fulfilling several unmet needs in the treatment of cancer. These include matrix metalloproteinase inhibitors (MMPis), continued expansion of biologics, photodynamic therapies (PDT), anti-angiogenics, and multiple drug resistance (MDR) modifiers. This market does not yet exist, though success of "cytostatic-like" treatments, such as hormonal therapies for prostate and breast cancer, suggests that the market potential for cytostatic agents could be significant.

Competition

The angiogenesis pipeline is very competitive, but this level of intensity is somewhat skewed by the large number of mechanistic approaches that are being claimed to demonstrate angiogenic activity. Furthermore, clear evidence of efficacy for these agents has not yet been demonstrated. For the purposes of this summary, only those compounds considered true anti-angiogenic compounds have been included. Companies with compounds in clinical development include Genentech, Entremed, Sugen, TAP, Magainin and Pharmacia Upjohn.

Angiogenesis Compounds in Clinical Development

Compound	Indications	Company	Phase
Neovastat	Solid tumors	Aeterna	III
RhuMab VEGF	Cancer	Genentech	II/III
Vitaxin	Arthritis, psoriasis, CVR	Ixsys	II
SU-5416	Cancer	Sugen	II/III
TNP 470	Cancer, arthritis	TAP	II
Thalidomide	Cancer	EntreMed/BMS	I
Squalamine, squalus	Cancer	Magainin	I
RPI 4610	Cancer	Ribozyne	I
VEGF antagonist	Cancer, retinopathy	NeXstar	I
Angiostatin/Endostatin	Cancer	EntreMed	I

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Unmet Needs

Cancer remains the second leading cause of death in the United States, Europe and Japan, and consequently, offers an attractive market opportunity for the pharmaceutical and biotechnology industries. This year about 563,100 Americans are expected to die of cancer, more than 1,500 people a day. In the US, 1 or 4 deaths is due to some form of cancer. In 1999, about 1,221,800 new cancer cases are expected to be diagnosed.

For most cancers, the level of physician satisfaction with current therapies is low. It has long been recognized by researchers, physicians, patients and family members that current treatment options may often be as devastating as the underlying disease.

Unmet needs in this market vary by tumor types and stages, with some tumors responding to treatment with better mortality and/or morbidity results than others. However, cancer is still treated as a terminal illness with significant shortcomings in present treatments. In general, unmet needs include:

Need	ABT-510 Attribute
Enhanced efficacy of therapeutic agents	Potential for enhanced efficacy
Reduced toxicity	Potential for reduced toxicity over current cytotoxic treatment
Improvements in drug administration	TBD
Improved target delivery of cytotoxics and novel therapeutics	Unknown
Proven outcomes data	Quality of Life and Pharmacoeconomics to be assessed

Considerations

Product Usage: Physicians have indicated that they would use anti-angiogenic agents initially in their more refractory patients, as follow-on or add-on to current best therapy (chemo or surgical). With experience and clinical evidence, they would be willing to use these agents in earlier stages of the disease, where they perceived the greatest benefit to be. Anti-angiogenesis agents are regarded as a maintenance therapy to be used in early disease or after primary therapy as a prophylactic process to prevent the spread of malignancy. Of course, their ultimate use will depend on the benefit provided, which cannot be determined until clinical trials have been completed. Efficacy evidence in humans manifested by tumor response of the magnitude seen in the preliminary dog studies would stimulate tremendous enthusiasm in the oncology community.

Product Benefits/Efficacy: Physicians are looking for improvements in time to tumor progression and prevention of metastases with cytostatic agents. There is a great deal of enthusiasm for this mechanism in the scientific and lay audience. The concept is very intuitive. Products, such as ABT-510, that promise a clinical benefit without the usual toxic trade-offs associated with current chemotherapeutic agents, will be enthusiastically received by oncologists.

Side Effects The proposed safety profile of anti-angiogenic agents may enhance usage, as the dose limiting toxicity profiles of most of the other available agents has established a much lower hurdle for demonstrating a preferred profile. However, as chronic therapy, anti-angiogenic agents may have to demonstrate a cleaner profile than cytotoxic agents do to ensure compliance.

Off-label use: Off label use accounts for between 30-60% of an oncology product's usage. Off-label use is driven by publication of clinical trial results in credible journals, listing in key compendia and/or a peer's experience with the product. Therefore, development spend for off-label use is considerably less than the spend required for regulatory approval of an indication. However, promotion of these off-label uses is limited.

Other indications: ABT-510 may be effective in other therapeutic roles, such as arthritic diseases and macular degeneration. These other indications may offer a commercial upside, through internal development or co-development/out-licensing opportunities.

Competition: While there are a relatively large number of angiogenesis inhibitors in development, it is unclear whether they will demonstrate a superior efficacy or side-effect profile vs. ABT-510. The mechanism of angiogenesis suggests that multiple anti-angiogenic approaches may be required to maximize the clinical benefit.

COGS: Initial estimates on finished cost of drug place it in the range of Lupron costs. Depending on final dosing requirements, the cost of this compound could become a significant obstacle. However, this will need to be considered in light of the pricing flexibility in the oncology market, where there is limited pricing sensitivity for products that are reimbursed. Any financial analysis will need to include royalty obligations to Northwestern University.

Dosing: There is still some uncertainty regarding the route of administration and feasible dosage forms for ABT-510. An "inconvenient" formulation leaves this product extremely vulnerable to competitors with more convenient dosage forms. A convenient dosage form, such as a monthly depot, will enhance product adoption over a less convenient form. However, the effect of the various dosage forms on product adoption will be dependent on the benefits the compound provides, side-effect profile and availability of competitive agents with more convenient dosage forms. For chronic therapy, convenience will play an important role in market penetration, given alternative agents. Although less convenient than oral therapy, parenteral therapy (depot, but not self-administered sub-cutaneous) is currently reimbursed by Medicare in the US. Over 60% of all cancer patients have Medicare as their primary healthcare coverage in the US.

Development/Regulatory: With a new class of compounds, there is not a clearly defined clinical development path or regulatory guidelines for reference. This hurdle is similar for all the competitive products, but increases the overall development risk profile for these agents. However, with several anti-angiogenic agents in late stage development, Abbott can learn from their experience.

Other Approaches: Other "cytostatic" approaches may present a competitive threat if they are used as substitutes. Due to the complexity of the pathogenesis of cancer, it is more likely that these agents will be used in combinations, but incremental benefits may become more difficult to demonstrate as the number of products and approaches multiply. This will require additional studies, as these other classes become part of standard cancer treatment. However, this threat is not unique to this compound.

Pricing: The treatment of cancer is expensive, so there is the potential for a great deal of pricing flexibility in this market. There is also an increasing emphasis on cost-effectiveness studies that will need to be addressed in the development plan.

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ABT - 518

Descriptive Memorandum

February 2001

Abbott Laboratories

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MMPI

Overview

Abbott's Matrix Metalloproteinase Inhibitor (MMPI) program represents a novel therapeutic class, with the potential to alter the way that cancer is treated by preventing or modifying disease progression and/or metastases. This more "chronic" approach to therapy has the potential to transform cancer into a disease that patients live with, much like the effect of HIV protease inhibitors on patients with AIDS. It also has the potential to expand the cancer market significantly by increasing the average length of treatment and expanding the pool of patients eligible to receive therapy.

The MMPs comprise a family of enzymes that degrade a wide range of matrix protein substrates. High expression of these enzymes occurs in cancer and is associated with the ability of tumors to grow, invade, develop new blood vessels and metastasize.

MMP inhibitors (MMPIs) may suppress the progression of tumors by several mechanisms:

- Suppress invasion/metastasis by blocking the membrane traversal and access to blood/lymphatic vessels
- Blocking the remodeling of extra-cellular matrix in the vicinity of primary tumors to prevent stroma-bound growth factors from stimulating tumor growth
- Blocking angiogenesis by preventing the proliferation and migration of endothelial cells and neovascularization of tumor.

Experimental evidence suggests that gelatinase A and gelatinase B are particularly important in tumor progression, consequently the project team has targeted gelatinase selective inhibitors for the treatment of cancer. Another reason for targeting highly gelatinase-selective MMP inhibitors relates to the side effect profile exhibited by broad-spectrum agents like marimastat. Chronic administration of marimastat causes a dose-limiting side-effect characterized by severe joint pain and stiffness. Since these joint effects may be mediated by inhibition of other MMPs like fibroblast collagenase, highly gelatinase selective agents may be efficacious without producing dose-limiting side effects.

The MMP selectivity profile exhibited by ABT-518 distinguishes it from competitor's compounds. ABT-518 possesses sub-nanomolar inhibition potencies versus both gelatinase A and gelatinase B and is substantially more selective for the inhibition of the gelatinases over fibroblast collagenase than marimastat and prinomastat. Despite its high selectivity, ABT-518 demonstrates antitumor activity equal or superior to prinomastat. Inhibition of tumor growth is dose dependent in both syngeneic and xenograft models. ABT-518 is also effective in blocking vessel formation in a mouse model of angiogenesis. ABT-518 is a stable crystalline solid which can be synthesized in six steps (25% overall yield) from commercial starting material.

ABT-518 gives rise to sustained plasma concentrations following single oral dosing in monkeys, dogs and rats. Bioavailabilities range between 68 and 93% depending on formulation and species. Several metabolites are produced after repeated oral dosing of ABT-518, although their relative amounts varies with gender and species.

ABT-518 displays no meaningful effects in genotoxicity, cytotoxicity and ligand binding assays and its cardiovascular effects in dogs are unremarkable. ABT-518 produces no significant toxic effects in rats treated with 100 mg/kg/day over 28 days. Plasma concentrations generated by ABT-518 in these studies are at least 20-fold higher than those necessary to produce efficacy in cancer animal models. ABT-518 is therefore a compelling development candidate with the potential to

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demonstrate antitumor effects superior to the MMP inhibitors currently undergoing clinical trials. Phase 1 clinical trials in cancer patients began March 2001.

The market

Currently, cytotoxic agents represent the largest, and fastest growing, class of oncology agents by sales volume. The following chart summarizes the value of the current oncology market.

Global Sales by Market Segment (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est)	CAGR '96-'98
Hormone	4,414	4,784	4,884	5,000	5.2%
Cytotoxic	4,278	5,212	6,268	7,300	21.0%
Adjunctive	3,367	3,651	4,166	4,900	11.2%
Total	12,059	13,647	15,318	17,200	12.7%

Source: Datamonitor

Sales by Region (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est)	CAGR '96-'98
US	5,564	6,276	7,422	8,500	15.5%
Ex- US	6,495	7,370	7,896	8,700	10.3%

Source: Datamonitor

Cytostatic agents have the potential to alter the way cancer is treated and presents opportunities for fundamentally new ways of approaching the disease. This cytostatic market does not yet exist, though success of more cytostatic "like" treatments, such as hormonal therapies for prostate and breast cancer, suggest that the market potential for cytostatic agents could be significant.

The ultimate commercial and clinical success of the MMPI will depend on the clinical benefit this product provides in key cancer types compared with current best therapy. These can be benefits provided by dosing this agent in addition to current therapy and/or as an alternative to best therapy, or as a new component of best therapy. All currently available products, including the market leaders such as Taxol, have significant shortcomings in their profiles.

However, as novel therapy, MMPIs will probably be adopted initially as add-on the current chemotherapy. As benefits are proven and clinical experience is gained, these agents may be used in earlier stages of cancer and/or in conjunction with surgery or radiation to prevent the progression of any microscopic disease that remains.

The clinical targets identified for this compound include late stage pancreatic cancer, late stage NSCL cancer (on-label), with late stage ovarian and breast cancer as additional cancer types where efficacy has been demonstrated, but not filed. Other cancer types this compound may be efficacious in include SCL, colorectal, bladder, stomach and prostate. Targets will be refined as we know more about this compound's in-vivo activity.

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The following tables summarize the key marketed competitive products by indication (US data only):

Late Stage Breast	
Product	Share
Cyclophosphamide/Cytoxan/BMS	18.7
Doxorubicin/Adriamycin/P&U	17.11
Docetaxel/Taxotere/RPR	16.25
Paclitaxel/Taxol/BMS	16.11
Trastuzumab/Herceptin/Genetech	11.26

Late Stage NSCL	
Product	Share
Carboplatin/Paraplatin/BMS	50.32
Paclitaxel/Taxol/BMS	44.14
Vinorelbine/Navelbine/Glaxo	22.78
Gemcitabine/Gemzar/Lilly	22.14
Cisplatin/Platinol/BMS	11.28

Late Stage Ovarian	
Product	Share
Paclitaxel/Taxol/BMS	47.11
Carboplatin/Paraplatin/BMS	45.42
Topotecan/Hycamtin/SKB	22.54
Dox SL/Doxil/Alza	9.14
Cisplatin/Platinol/BMS	7.58

Late Stage Pancreas	
Product	Share
Gemcitabine/Gemzar/Lilly	78.5
5-FU/Efudex/ICN Pharma	21.0
Leucovorin/	10.7
Cisplatin/Platinol/BMS	4.72

Compounds in Development

The MMP inhibitor field is competitive. More than 30 firms have filed patents claiming small molecule MMP inhibitors over the past 5 years, and several companies have compounds in advanced clinical development. Abbott's compound may be 3rd or 4th to market and will have to demonstrate a competitive advantage to gain the share necessary to support the clinical development of this compound. Companies with compounds in advanced clinical development for the treatment of cancer include Agouron/Warner Lambert/Pfizer, British Biotechnology/Schering Plough and BMS and are listed below. Other companies are targeting this mechanism for arthritis.

MMPis in Clinical Development for Cancer

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Compound	Company	Comments	Phase
Marimistat	BritishBiotechnology/ Schering Plough	Broad spectrum, dose limiting toxicity. Activity seen in gastric cancer, but negative results in pancreatic.	III
Prinomastat	Agouron/ Wamer Lambert/ Pfizer	Moderate gelatinase selectivity, dose limiting toxicity. May be dosing sub-optimally to avoid toxicity. Efficacy data not available.	III
BMS 275291	BMS	Broad spectrum, joint effects seen in Phase I studies.	II

Bayer recently dropped development of BAY 12-9566 due to concerns about potential toxicity. Recent results from a study with marimistat in pancreatic cancer, where adding marimistat to Gemzar resulted in no survival advantage, has led to speculation that MMPs may be more applicable in less aggressive cancer types or earlier stages of the disease. Alternatively, it could be a reflection of the inability to examine higher doses of marimastat due to joint effects.

The joint effects produced by the compounds listed above almost certainly preclude their long-term use, limit compliance and reduce optimal efficacy. Any MMP inhibitor that lacks these side effects will possess a substantial competitive advantage. The musculoskeletal effect produced by marimastat and prinomastat in cancer patients is typically described as arthralgia, myalgia and tendinitis, which occurs predominately in the upper limbs. While mild cases respond to analgesics, interrupting therapy for a period of approximately 2 weeks is necessary when the condition is less well tolerated.

Although Abbott's timing to market is not optimal, the shortcomings of the competitive products provide an opportunity for a compound with an improved SE or efficacy profile. Current animal models seem to predict Abbott's compound is superior to those currently in clinical trials, and has the potential to be best in class.

Product profile

The objective of a product profile at this time in the product's development is to provide a target for the types of attributes that will be required to be commercially successful. This profile is based on market research with oncologists and consultation with opinion leaders. This profile will continue to be refined as more is known about this product's profile, development of competitive products and the market continues to evolve.

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	Base	Optimal
Efficacy	ABT-518, alone or in combination with best therapy, provides at least one of	Provides more than one of the efficacy benefits outlined.

	the following benefits in at least one solid tumor type: <ul style="list-style-type: none"> • Increased survival • Tumor regression • Improved quality of life • Increased time to tumor/disease progression 	
Competitive advantage	ABT-518 will need to demonstrate a clinically significant advantage in efficacy (see parameters above) or additive synergistic activity with current/competitive agents or clinically significant advantage in side-effect profile relative to other MMPi agents.	Same
Administration	Convenient administration relative to competitive agents.	Same plus reimbursement in US market.
COGS	A finished cost of goods that is consistent with at least an 80% standard manufacturing margin.	A finished cost of goods that is consistent with at least a 90% standard manufacturing margin.

Marketing overview

Product Usage: Physicians have indicated that they would use MMPis initially in their more refractory patients, as follow-on or add-on to current best therapy (chemo or surgical). With experience and clinical evidence, they would be willing to use these agents in earlier stages of the disease, where they perceived the greatest benefit to be. The MMPi was regarded as a maintenance therapy to be used in early disease or after primary therapy as a prophylactic process to prevent the spread of malignancy.

Product Benefits/Efficacy: Physicians are looking for improvements in time to tumor progression and prevention of metastases with cytostatic agents. The MMPi mechanism has more recently been implicated as having an even more active role in cancer pathogenesis, from preventing primary tumor growth to anti-angiogenic properties. Positive results from competitive agents, such as marimistat in gastric cancer, provides proof of principle for this mechanism.

Side Effects: The proposed safety profile of MMPis (excluding joint toxicity) may enhance usage, as the dose limiting toxicity profiles of most of the other available agents has established a much lower hurdle for demonstrating a preferred profile. However, as chronic therapy, MMPis may have to demonstrate a cleaner profile than cytotoxic agents do to ensure compliance. As the 3rd or 4th MMPi to market, SE hurdles will be even higher for this compound. As a critical Go/No Go decision point, the joint toxicity of this compound will be evaluated in an expanded Phase I multi-dose study.

Dosing: Discovery is currently targeting an oral dosage form. In general, oral therapies are acknowledged by physicians and patients as being more convenient to the patient. Chronic oral dosing may also reduce overall costs, as infusion support products and personnel would not be required, enhancing pharmacoeconomic evidence.

COGS: Initial estimates on finished cost of drug suggest that drug costs will not be significant for this compound

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Off-label use: Off label use accounts for between 30-60% of an oncology product's usage. Off-label use is driven by publication of clinical trial results in credible journals, listing in key compendia and/or a peer's experience with the product. Therefore, development spend for off-label use is considerably less than the spend required for regulatory approval of an indication. However, promotion of these off-label uses is limited.

Competition: As the 3rd or 4th MMPi to market, Abbott's compound will need to demonstrate a meaningful clinical advantage over compounds that are in more advanced development. Strict Go/No Go criteria will determine if the MMPi can meet these hurdles. If they cannot be met, the compound will not move forward.

Development/Regulatory: With a new class of compounds, there is not a clearly defined clinical development path or regulatory guidelines for reference. This hurdle is similar for all the competitive products, but increases the overall development risk profile for these agents. However, with several MMPis in late stage development, Abbott can learn from their experience.

Other Approaches: Other "cytostatic" approaches may present a competitive threat if they are used as substitutes. Due to the complexity of the pathogenesis of cancer, it is more likely that these agents will be used in combinations, but incremental benefits may become more difficult to demonstrate as the number of products and approaches multiply. This will require additional studies, as these other classes become part of standard cancer treatment. However, this threat is not unique to this compound.

Pricing: The treatment of cancer is expensive, so there is the potential for a great deal of pricing flexibility in this market. However, as an oral therapy in the US market, there may be additional downward price pressure for this agent. There is also an increasing emphasis on cost-effectiveness studies that will need to be addressed in the development plan.

Dosing: Discovery is currently targeting an oral dosage form. In general, oral therapies are preferred by physicians and patients because of the convenience to the patient. However, this form may not be the best choice for some people who already have certain digestive system symptoms (vomiting, diarrhea, or severe nausea), cannot swallow liquids or pills, or cannot remember when or how many pills to take. Additionally, in the US market there are several unique factors that currently do not favor oral therapies. Novel oral therapies are not currently reimbursed by Medicare, a significant payer for the oncology patient population. Also, 40-60% of a community oncologist's income is generated through the administration of IV drugs. An oral therapy would not be a source of revenue to the physician.

Clinical Studies

Clinical studies across a wide range of solid tumors will be initiated, including but not limited to breast cancer, non small cell lung cancer, ovarian cancer, pancreatic cancer, etc...

Final indications pursued will depend from the results of the phase II studies.

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Farnesyltransferase Inhibitor

Descriptive Memorandum

February 2001

Abbott Laboratories

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Overview

The Ras genes were the first oncogenes of mammalian origin to be discovered. Intensive research over the last decade has led to the elucidation of the normal function of cellular Ras protein, the role of Ras mutations in oncogenic transformation, and the identification of molecular targets, such as the enzyme farnesyltransferase, for inhibiting Ras activity. Although farnesyltransferase inhibitors (FTIs) were initially designed with the intention of inhibiting the posttranslational prenylation, and hence function, of Ras, it is now becoming apparent that farnesylated proteins other than Ras (e.g., RhoB) are also critical for malignant growth and may be the relevant target for inhibition of farnesylation. While it remains controversial whether blocking Ras activity or altering the RhoB prenylation status is the actual function of an FTI, these agents, exemplified by ABT-839 and FTIs in the clinic, exhibit remarkable anticancer activity against a wide variety of tumors in preclinical models. The current FTI program is projected to reach DDC status in January, 2001.

Abbott evaluated one FTI, ABT-839, in normal volunteers, but decided to discontinue development of this drug due to its poor pharmacokinetic profile. Invaluable experience was gained, however, from both the preclinical and clinical studies with this compound. Abbott's second-generation series are novel structures that exhibit significantly improved potency and oral bioavailability.

There continues to be tremendous enthusiasm in the medical community and pharmaceutical industry for this mechanism of action. Farnesyltransferase inhibitors have demonstrated impressive antitumor activity in preclinical models with activity equivalent to or better than that achieved with conventional cytotoxic chemotherapy given at the maximal tolerated dose. These agents appear to inhibit angiogenesis and, consistent with this activity, minimal resistance has been observed in preclinical models. The potential also exists for synergistic activity in combination with cytotoxic chemotherapy.

The market

Cancer remains the second leading cause of death in the US, and consequently is an attractive market opportunity for the pharmaceutical/biotechnology industries. Approximately 40% of all Americans will develop cancer in their lifetime.

The worldwide cytotoxic and hormonal cancer therapies market is highly fragmented with only BMS and Zeneca holding a greater than 10% market share. Although the market is not concentrated, the field is highly competitive with more than 60 companies focused on the cancer research area. The growth of the oncology market is fueled by increasing disease incidence, new product entries, new therapeutic approaches, a growing adjunct therapy market that expands the number of patients eligible for chemotherapy, and intensified research competition. The data in Tables 1 and 2 summarize the value of the current oncology market. A great deal of uncertainty surrounds the concept of cytostatic treatment of cancer. Conceptually it may transform the way cancer is treated, allowing patients longer disease free survival and improved quality of life. However, at this point in development, this paradigm does not exist in cancer. Considering market, clinical and patient dynamics factors, breast, colorectal, prostate and non-small cell lung cancers are the most attractive targets for development.

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Table 1. Global sales by market segment (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est.)	CAGR '96-'98
Hormone	4,414	4,784	4,884	5,000	5.2%
Cytotoxic	4,278	5,212	6,268	7,300	21.0%
Adjunctive	3,367	3,651	4,166	4,900	11.2%
Total	12,059	13,647	15,318	17,200	12.7%

Source: Datamonitor

Table 2. Sales by region (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est.)	CAGR '96-'98
US	5,564	6,276	7,422	8,500	15.5%
Ex- US	6,495	7,370	7,896	8,700	10.3%

Source: Datamonitor

Cytostatic agents have the potential to alter the way cancer is treated and presents opportunities for fundamentally new ways of approaching the disease. This cytostatic market does not yet exist, though success of more cytostatic "like" treatments, such as hormonal therapies for prostate and breast cancer, suggest that the market potential for cytostatic agents could be significant.

The ultimate commercial and clinical success of the FTI will depend on the clinical benefit this product provides in key cancer types compared with current best therapy. These can be benefits provided by dosing this agent in addition to current therapy and/or as an alternative to best therapy, or as a new component of best therapy. All currently available products, including the market leaders such as Taxol, have significant shortcomings in their profiles.

However, as novel therapy, FTIs will probably be adopted initially as add-ons to current chemotherapy. As benefits are proven and clinical experience is gained, these agents may be used in earlier stages of cancer and/or in conjunction with surgery or radiation to prevent the progression of any microscopic disease that remains.

The clinical targets identified for this compound include late stage pancreatic cancer, late stage NSCL cancer (on-label), with late stage ovarian and breast cancer as additional cancer types where efficacy has been demonstrated, but not filed. Other cancer types this compound may be efficacious in include SCL, colorectal, bladder, stomach and prostate. Targets will be refined as we know more about this compound's in-vivo activity.

The following tables summarize the key marketed competitive products by indication (US data only):

Late Stage Breast	
Product	Share
Cyclophosphamide/Cytoxan/BMS	18.7
Doxorubicin/Adriamycin/P&U	17.11
Docetaxel/Taxotere/RPR	16.25
Paclitaxel/Taxol/BMS	16.11
Trastuzumab/Herceptin/Genetech	11.26

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Late Stage NSCL	
Product	Share
Carboplatin/Paraplatin/BMS	50.32
Paclitaxel/Taxol/BMS	44.14
Vinorelbine/Navelbine/Glaxo	22.78
Gemcitabine/Gemzar/Lilly	22.14
Cisplatin/Platinol/BMS	11.28

Late Stage Ovarian	
Product	Share
Paclitaxel/Taxol/BMS	47.11
Carboplatin/Paraplatin/BMS	45.42
Topotecan/Hycamtin/SKB	22.54
Dox SL/Doxil/Alza	9.14
Cisplatin/Platinol/BMS	7.58

Late Stage Pancreas	
Product	Share
Gemcitabine/Gemzar/Lilly	78.5
5-FU/Efudex/CN Pharma	21.0
Leucovorin/	10.7
Cisplatin/Platinol/BMS	4.72

Emerging science within the past decade has radically altered the paradigm for cancer therapy and presents opportunities for fundamentally new ways of approaching the disease. Abbott has multiple discovery cytostatic targets, which may improve effective, but we are not alone: more than 200 compounds from other players are in development. The goal of cytostatic therapy is to improve quality of life, controlling the disease and transforming aggressive treatment to a chronic condition, which has been compared to the impact of protease inhibitors on the course of HIV.

Clinical Studies

Considering all the factors, market, clinical and patient dynamics, breast, colorectal, prostate and non-small cell lung cancer appear to be the most attractive targets for development. The development of cytostatic agents faces a number of challenges as regulatory agencies and physicians evaluate the new emerging paradigm of cancer therapy.

Despite the enormous medical need, drugs for chronic treatment/disease stabilization and improved quality of life for cancer patients do not yet exist. Correspondingly, animal models test efficacy that has not yet been validated as predictive of response in humans. Medical oncologists have historically depended on determination of maximum tolerated dose and response manifested by tumor shrinkage for cancer drug development. These parameters are not relevant to novel "cytostatic" agents. Combination with conventional cytotoxic drugs will be required in the near term and will have to be determined empirically. Intermediate and surrogate measures of biological response will have to be developed. Regulatory agencies are grappling with the same issues.

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Competition:Within Project Approach

Company	Compound	Indication	Status of compound	Status of project
Janssen Pharmaceutica	R-11577 (A-251076)	Cancer (unspecified)	Phase III	active
Schering-Plough	Sch66336 (A-285622)	Cancer (unspecified)	Phase II	active
Merck	L-778123	Cancer (unspecified)	Phase I (I.V.) abandoned	unknown
Bristol-Myers Squibb	BMS-214662	Cancer (unspecified)	Phase I	active
LG Chemical	LB 42908	Cancer (unspecified)	preclinical	active
Rhône-Poulenc Rorer	quinocidine derivatives	Cancer (unspecified)	preclinical	active
Pfizer	unknown structure	Cancer (unspecified)	preclinical	active
Parke-Davis	unknown structure	Cancer (unspecified)	preclinical	abandoned project
Roche	peptidomimetics	Cancer (unspecified)	preclinical	abandoned project
Eli Lilly	peptidomimetics	Cancer (unspecified)	preclinical	unknown
Banyu	PPP mimetic	Cancer (unspecified)	preclinical	active
ISIS	ISIS-2503 (nas antisense)	Cancer (unspecified)	Phase I	active

Within Therapeutic Area

Approach	Selected Compounds	Company(ies)	Status
antisense	ISIS 3521, ISIS, 5132	ISIS	phase I
cytotoxic agents	camptotecin, CI-980, farestroin, Genzar, Hycamtin, Indarubicin, Novantrone, Onconase, Capecitabine, Tomudex	P&U, Warner-Lambert, Schering, Lilly, SKB, P&U, Immunex, Allacell, Roche, Zeneca	most phase III
differentiation	targretin, panretin, 5-azacytidine	Ligand, NCI	Ligand in phase II/III
drug resistance modifiers	VX-710, 776C85, RMP-7, CT-2584	Vertex, Glaxo Wellcome, Alkermes, Cell Therapeutics	Vertex in phase II
gene therapy	Onyx-015, MDR-1, GLI-328, IL-2, GV-1301	Onyx, Introgen, Therion Biologics, Theragen, Genetic Therapy, Cyclacel, RPR Genocel, GeneMedicine, Titan, etc	Restricted to accessible cancers. Most advanced: Phase VII
hormonal therapy	Zolodex, amideks, droloxiden, Oncolar, Folvizor, Casodex, rogletimide	Zeneca, Pfizer, Novartis, Janssen, US bioscience	most phase III
immunotherapy			
antibodies	IDEC-Y2A2B8, anti-HER2, anti EGFR	IDEC, Genetech, ImClone	IDEC recently approved, others phase III
cytokines	IL-12, IL-4, Prolestin, Roferon-A	Roche, Schering, Chiron, Roche	phase III
vaccines	rV-gp100, Genevax, MGv	Apollon, Therion, Progenics	phase I, II
photodynamic	photofrin, promycin	QLT photo, Vion	phase III
radiation sensitizers	Nex-Sensamide, radinyl	Ordene, Roberts	phase II, III
metalloproteinase inhibitors	marimastat, AG-3340, CGS-27023A	British Biotech, Agouron, Novartis, Bayer	BBT in phase III
angiogenesis inhibitors	TNP-470, SU-5416, anti VEGF-mAb, thalidomide, DC101	TAP, Sugen, Genentech, Entremed, ImClone, etc	see angiogenesis project review for details

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Competitive Analysis

The project is on par with others in the industry. While second generation Abbott compounds are not yet in clinic, all of the compounds from other companies that are in clinical trials have deficiencies. While the Schering compound has the best oral PK profile, it is not particularly potent. The Janssen compound is potent, but has a poor PK profile. The Merck compound exhibited QTc prolongation and development has been stopped. The Bristol Myers Squibb compound, BMS-214662, which is in phase I, is an *in vitro* submicromolar inducer of apoptosis in human tumor cells and appears to be the most potent inducer of apoptosis of the known FTIs. This compound could have a different mechanism of action from the classical FTIs and have its own liabilities. LG42908 from LG Chemical is potent FTI and has good oral bioavailability (F=91% in monkey), however, it's a CYP3A4 inhibitor and will have significant drug-drug interaction liabilities. Extensive preclinical pharmacology at Abbott has defined optimum parameters for a FTase inhibitor that may not be known to our competitors, or be achievable with the current generation of FTIs. Although not yet established, we anticipate that the Abbott compound will be improved over competitors' compounds with respect to potency, oral bioavailability, half-life, toxicity, efficacy, angiogenesis inhibition, and lack of resistance.

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**DOPAMINE RECEPTOR AGONIST
PROGRAM**

Descriptive Memorandum

February 2001

Abbott Laboratories

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JH 008206**

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D4 Agonists for Male Erectile Dysfunction

Scientific Overview

Male erectile dysfunction (MED) is defined as the "inability to maintain an erection sufficient for satisfactory sexual intercourse" (NIH Consensus Panel) and results from physiological (organic), psychogenic causes, or a combination thereof. This disorder is associated with decreased quality of life, including personal well being, and diminished family and social relationships. In 1999, an estimated 77 million men over the age of 40 (52% of men over 40 years-old) in the seven major pharmaceutical markets experienced some degree of MED, and the prevalence increases with age. Approximately 10-20% of patients have severe or complete MED, and the majority of the population suffers from moderate disease. While the introduction of Viagra has increased the diagnosis rate of MED in the U.S., 75% or more of patients do not seek treatment. However, as the "baby boomer" generation ages, MED will become a more prominent concern and a growing number of patients are likely to seek treatment.

Abbott's male erectile dysfunction program targeting D4 dopamine receptors represents a novel therapeutic approach to the rapidly growing male erectile dysfunction (MED) market. The current gold standard for the treatment of MED, Viagra, acts peripherally at the penile smooth muscle level to induce erection by modulating the levels of cGMP. In contrast, a selective D4 dopamine agonist will act in the brain at the sites necessary for initiation of a successful erection. Targeting the D4 receptors in brain offers the potential for efficacy in patients with MED that do not respond to Viagra (for example patients with diabetes). Additionally, targeting D4 receptors should not result in any cardiovascular adverse events unlike Viagra which can cause serious cardiovascular effects in patients who are on nitroglycerine-based medications. Since safety is of paramount importance for any life-style disorder like MED, a new agent that does not have any contraindications or warnings related to safety issues may be positioned to become the gold-standard therapy.

Evidence for the potential of a selective D4 dopamine receptor agonist for the treatment of erectile dysfunction includes:

- The non-selective dopamine receptor agonist apomorphine (UprimaTM) has been shown to be effective in phase III clinical trials, and has received scientific approval for market in the EU, for the treatment of MED. This validates the utility of dopaminergic agonists to facilitate penile erections in humans. However, the clinical development of apomorphine for the US market has been hampered by dose limiting side-effects (emesis and syncope).
- Studies at Abbott have established that the efficacy of apomorphine (penile erection) and side-effect (emesis) are mediated by different dopamine receptor subtypes. There are 5 known dopamine receptors. Abbott scientists have discovered that the selective activation of D₄ receptors can facilitate penile erection in animals, while the D₂ receptor appears to mediate the emetic effect of apomorphine. The discovery of a D₄ selective agonist maximizes the possibility to identify a compound with equivalent/superior efficacy to apomorphine but devoid of its side-effect liabilities.

PPD is currently screening the Abbott library of compounds to identify novel and proprietary D4 dopamine receptor compounds. Initial hits have been identified that are as potent as any known D4 dopamine receptor agonist. The strategy is to aggressively profile these hits for selectivity across the five different dopamine receptor subtypes and to ensure that selective agents are effective in a number of preclinical in vivo models of MED and have no emetic or cardiovascular side effects. The D4 dopamine receptor agonist program will be discontinued if selective D4 agonists do not achieve at least a 30-fold separation between efficacy in a model of MED and cardiovascular/emetic side effects.

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Abbott has a competitive advantage in the race to exploit selective D4 dopamine receptor agonists for MED. A patent application covering the use of any selective D4 agonist for the treatment of MED has been filed and no other pharmaceutical company may have the range of preclinical models of efficacy and safety in addition to access to the clinical information gained from the development of apomorphine. Our molecular modeling group has facilitated advances in the design of selective D4 agonists.

Market Analysis

The introduction of Viagra combined with increased disease awareness resulted in the MED market in the US exploding from \$157MM in 1997 to an estimated \$726MM in 2000. Worldwide, this market has seen similar growth, and is estimated at \$500MM for ex-US for 2000. Viagra currently dominates the MED market, with more than \$1 billion in sales in the \$1.3 billion worldwide market in 1999, and >95% of the MED prescriptions in the US. The market growth is expected to continue, with an estimated CAGR in the US of 17.9% (2000 – 2005), fueled by increased awareness of MED, expanded use to wider patient segments for relationship or performance enhancement, and the introduction of heavily promoted new agents. Downward pressure on growth will come from continued perceptions of safety concerns, the limited efficacy of Viagra™, and out-of-pocket cost to patients.

Market drivers influencing the potential of a D4 dopamine receptor agonist include:

- Patient Awareness and Demand Viagra has built considerable awareness of MED. However, in the US, only 10-25% of current MED patients seek treatment for this disorder. Ex-US the percentage of patients seeking treatment is lower (10%). This is mainly due to the lack of DTC promotional campaigns in the ex-US markets. Further market expansion requires continued patient and physician education.
- Product Safety: There are growing patient and regulatory concerns regarding the safety of Viagra. While, physicians currently perceive Viagra™ to be safe, if used by the correct patients, there is significant concern regarding the concomitant use of nitrates for cardiovascular disorders with Viagra. Approximately 10% of Viagra patient deaths have been attributed to use of nitrates. Thus, there is an opportunity to eliminate this concern for physicians and to expand the market.
- Product Efficacy: In clinical trials Viagra allowed successful intercourse in about 50% of attempts. The limited and inconsistent efficacy of the product has resulted in patient dissatisfaction and discontinuation, thus creating a chance to drive Viagra quitters or switchers, as well as new patients, to new, more effective, MED products. The demonstration of efficacy in a broader population of MED patients might also influence physicians to try an alternative product prior to Viagra. The delay in onset (~1hr) and the variability in onset of action from patient to patient is an additional complaint about Viagra. Product features of a selective D4 agonist such as a more rapid onset of action or more reproducible onset will have a positive influence on the market opportunity for MED therapies.
- Additional Indications: Use of a D4 dopamine receptor agon in other indications such as "relationship enhancement" (female sexual dysfunction and age-related decline in male sexual performance) offers an opportunity to both expand the potential market to include women and non-MED sufferers, and reduce the embarrassment of MED for patients. Additional research is required to identify meaningful endpoints in this expanded indication. Initial studies conducted by Pfizer showed that Viagra™ was not effective to treat female sexual dysfunction.

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Competitive Overview

The following tables summarize the key competitive activities in regard to marketed products and products in the development pipeline. To date there are no reports any other company targeting selective D4 agonists for the treatment of MED, although a number of companies do have activities in the dopamine receptor arena for other indications that could be re-focused to MED if they became aware of Abbott's insights into the D4 receptor.

A. Oral agents

Approach	Compound/Product	Company(ies)	Status
PDE5 inhibition	Sildenafil (Viagra TM)	Pfizer	Marketed
DA receptor	Apomorphine (Uprima TM)	TAP	NDA filing withdrawn
Adrenergic	Phenolamine (Vasomax TM)	Schering-Plough/Zenagen	NDA filing on hold (>1 year)
PDE5 inhibition	IC351 (Cialis TM)	ICOS-Lilly	Phase III
PDE5 inhibition	Vardenafil	Bayer	Phase II-III

B. Intranasal

Approach	Compound/Product	Company(ies)	Status
DA receptor	Nasal apomorphine	Nastech	Phase II

C. Intracavernosal agents

Approach	Compound/Product	Company(ies)	Status
EP receptor	PGE ₁ (Caverjel TM , Edex TM)	Pharmacia, Schwarz Pharma	Marketed
VIP receptor/ Adrenergic	VIP-phenolamine (Invicorp TM)	Senetek	Marketed outside US
K channels	PNU 83757	Pharmacia	Phase II

D. Intraurethral agents

Approach	Compound/Product	Company(ies)	Status
EP receptor	PGE ₁ (Muse TM)	Vivus, Abbott	Marketed

E. Topical

Approach	Compound/Product	Company(ies)	Status
EP receptor	PGE ₁ (Alprox-TD; Topiglan)	NexMed, MacroChem	Phase II and III

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March 13, 2001

John Hancock Life Insurance Company
Investors Partner Life Insurance Company
John Hancock Variable Life Insurance Company
Attention: Stephen J. Blewitt
John Hancock Place
P.O. Box 111
Boston, MA 02117

Ladies and Gentlemen,

I have acted as counsel for Abbott Laboratories, an Illinois corporation (the "Company"), in connection with the Company's collaboration with John Hancock Life Insurance Company, a Massachusetts corporation, Investors Partner Life Insurance Company, a Massachusetts corporation, John Hancock Variable Life Insurance Company, a Delaware corporation (collectively, "John Hancock") pursuant to the Research Funding Agreement made as of March 13, 2001 (the "Research Funding Agreement"). Capitalized terms used herein without definition have the meanings assigned to them in the Research Funding Agreement.

In connection with the opinions expressed herein, I have made such examination of matters of law and of fact as I considered appropriate or advisable for purposes hereof. As to matters of fact material to the opinions expressed herein, I have relied upon certificates and statements of government officials and of officers of the Company. I have also examined originals or copies of such corporate documents or records of the Company as I have considered appropriate for the opinions expressed herein. I have assumed for the purposes of this opinion the genuineness of all signatures (other than those of individuals signing on behalf of the Company which are genuine), the legal capacity of natural persons, the authenticity of the documents submitted to me as originals, the conformity to the original documents of all documents submitted to me as certified, facsimile or photostatic copies, and the authenticity of the originals of such copies.

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JH 008210

MAR. 13. 2001 12:29PM

NO. 2199 P. 3/3

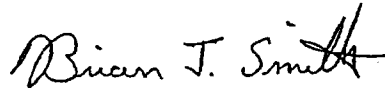
John Hancock Life Insurance Company
Investors Partner Life Insurance Company
John Hancock Variable Life Insurance Company
March 13, 2001
Page 2

Based upon the foregoing, and subject to the qualifications and limitations stated herein, I am of the opinion that: (i) the Company is duly organized, validly existing and in good standing in the State of Illinois; (ii) the Company has the requisite corporate power and authority to execute, deliver and perform the Research Funding Agreement; (iii) the Research Funding Agreement has been duly and validly authorized by the Company, and duly executed and delivered by an authorized officer of the Company and constitutes a valid and binding legal obligation of the Company enforceable against it in accordance with its terms; (iv) the performance of the Research Funding Agreement by the Company does not constitute a breach or violation of its organizational documents or any other agreement or understanding, written or oral, to which the Company is a party or any existing law, statute, rule or regulation by which the Company is bound; (v) no consents or approvals of any court or governmental authority is required on the part of the Company in connection with the execution, delivery, and performance of the Research Funding Agreement; (vi) there is no litigation pending, or to my knowledge threatened, which calls into question the validity of the Research Funding Agreement.

My opinion expressed above is limited to the law of the State of Illinois and the federal law of the United States, and I do not express any opinion herein concerning any other law.

The opinion set forth herein is rendered only to you and solely for your benefit in connection with the above described transactions. This opinion may not be relied upon by you for any other purpose, or relied upon by any other person for any purpose, without my prior written consent.

Very truly yours,



Leonard Deposition Exhibit 3

P's Exhibit 1

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Matrix Metalloproteinase Inhibitors Program

Descriptive Memorandum

May 2000

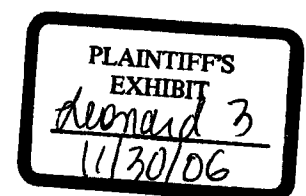
Abbott Laboratories

May 31st, 2000

Hancock_MMPI

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ABBT246447



MMP1**Overview**

Abbott's Matrix Metalloproteinase Inhibitor (MMPi) program represents a novel therapeutic class, with the potential to alter the way that cancer is treated by preventing or modifying disease progression and/or metastases. This more "chronic" approach to therapy has the potential to transform cancer into a disease that patients live with, much like the effect of HIV protease inhibitors on patients with AIDS. It also has the potential to expand the cancer market significantly by increasing the average length of treatment and expanding the pool of patients eligible to receive therapy.

The MMPs comprise a family of enzymes that degrade a wide range of matrix protein substrates. High expression of these enzymes occurs in cancer and is associated with the ability of tumors to grow, invade, develop new blood vessels and metastasize.

MMP inhibitors (MMPis) may suppress the progression of tumors by several mechanisms:

- Suppress invasion/metastasis by blocking the membrane traversal and access to blood/lymphatic vessels
- Blocking the remodeling of extra-cellular matrix in the vicinity of primary tumors to prevent stroma-bound growth factors from stimulating tumor growth
- Blocking angiogenesis by preventing the proliferation and migration of endothelial cells and neovascularization of tumor.

Experimental evidence suggests that gelatinase A and gelatinase B are particularly important in tumor progression, consequently the project team has targeted gelatinase selective inhibitors for the treatment of cancer. Another reason for targeting highly gelatinase selective MMP inhibitors relates to the side effect profile exhibited by broad-spectrum agents like marimastat. Chronic administration of marimastat causes a dose-limiting side-effect characterized by severe joint pain and stiffness. Since these joint effects may be mediated by inhibition of other MMPs like fibroblast collagenase, highly gelatinase selective agents may be efficacious without producing dose-limiting side effects.

The MMP selectivity profile exhibited by ABT-518 distinguishes it from competitor's compounds. ABT-518 possesses sub-nanomolar inhibition potencies versus both gelatinase A and gelatinase B and is substantially more selective for the inhibition of the gelatinases over fibroblast collagenase than marimastat and prinomastat. Despite its high selectivity, ABT-518 demonstrates antitumor activity equal or superior to prinomastat. Inhibition of tumor growth is dose dependent in both syngeneic and xenograft models. ABT-518 is also effective in blocking vessel formation in a mouse model of angiogenesis. ABT-518 is a stable crystalline solid which can be synthesized in six steps (25% overall yield) from commercial starting material.

ABT-518 gives rise to sustained plasma concentrations following single oral dosing in monkeys, dogs and rats. Bioavailabilities range between 68 and 93% depending on formulation and species. Several metabolites are produced after repeated oral dosing of ABT-518, although their relative amounts varies with gender and species.

ABT-518 displays no meaningful effects in genotoxicity, cytotoxicity and ligand binding assays and its cardiovascular effects in dogs are unremarkable. ABT-518 produces no significant toxic effects in rats treated with 100 mg/kg/day over 28 days. Plasma concentrations generated by ABT-518 in these studies are at least 20-fold higher than those necessary to produce efficacy in cancer animal models. ABT-518 is therefore a compelling development candidate with the

potential to demonstrate antitumor effects superior to the MMP inhibitors currently undergoing clinical trials.

The market

Currently, cytotoxic agents represent the largest, and fastest growing, class of oncology agents by sales volume. The following chart summarizes the value of the current oncology market.

Global Sales by Market Segment (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est)	CAGR '96-'98
Hormone	4,414	4,784	4,884	5,000	5.2%
Cytotoxic	4,278	5,212	6,268	7,300	21.0%
Adjunctive	3,367	3,651	4,166	4,900	11.2%
Total	12,059	13,647	15,318	17,200	12.7%

Source: DataMonitor

Sales by Region (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est)	CAGR '96-'98
US	5,564	6,276	7,422	8,500	15.5%
Ex- US	6,495	7,370	7,896	8,700	10.3%

Source: DataMonitor

Cytostatic agents have the potential to alter the way cancer is treated and presents opportunities for fundamentally new ways of approaching the disease. This cytostatic market does not yet exist, though success of more cytostatic "like" treatments, such as hormonal therapies for prostate and breast cancer, suggest that the market potential for cytostatic agents could be significant.

The ultimate commercial and clinical success of the MMPi will depend on the clinical benefit this product provides in key cancer types compared with current best therapy. These can be benefits provided by dosing this agent in addition to current therapy and/or as an alternative to best therapy, or as a new component of best therapy. All currently available products, including the market leaders such as Taxol, have significant shortcomings in their profiles.

However, as novel therapy, MMPis will probably be adopted initially as add-on to the current chemotherapy. As benefits are proven and clinical experience is gained, these agents may be used in earlier stages of cancer and/or in conjunction with surgery or radiation to prevent the progression of any microscopic disease that remains.

The clinical targets identified for this compound include late stage pancreatic cancer, late stage NSCL cancer (on-label), with late stage ovarian and breast cancer as additional cancer types where efficacy has been demonstrated, but not filed. Other cancer types this compound may be efficacious in include SCL, colorectal, bladder, stomach and prostate. Targets will be refined as we know more about this compound's in-vivo activity.

The following tables summarize the key marketed competitive products by indication (US data only):

Late Stage Breast	
Product	Share
Cyclophosphamide/Cytoxan/BMS	18.7
Doxorubicin/Adriamycin/P&U	17.11
Docetaxel/Taxotere/RPR	16.25
Paclitaxel/Taxol/BMS	16.11
Trastuzumab/Herceptin/Genetech	11.26

Late Stage NSCL	
Product	Share
Carboplatin/Paraplatin/BMS	50.32
Paclitaxel/Taxol/BMS	44.14
Vinorelbine/Navelbine/Glaxo	22.78
Gemcitabine/Gemzar/Lilly	22.14
Cisplatin/Platinol/BMS	11.28

Late Stage Ovarian	
Product	Share
Paclitaxel/Taxol/BMS	47.11
Carboplatin/Paraplatin/BMS	45.42
Topotecan/Hycamtin/SKB	22.54
Dox SL/Doxil/Alza	9.14
Cisplatin/Platinol/BMS	7.58

Late Stage Pancreas	
Product	Share
Gemcitabine/Gemzar/Lilly	78.5
5-FU/Efudex/ICN Pharma	21.0
Leucovorin/	10.7
Cisplatin/Platinol/BMS	4.72

Compounds in Development

The MMP inhibitor field is competitive. More than 30 firms have filed patents claiming small molecule MMP inhibitors over the past 5 years, and several companies have compounds in advanced clinical development. Abbott's compound may be 3rd or 4th to market and will have to demonstrate a competitive advantage to gain the share necessary to support the clinical development of this compound. Companies with compounds in advanced clinical development for the treatment of cancer include Agouron/Varnier Lambert/Pfizer, British Biotechnology/Schering Plough and BMS and are listed below. Other companies are targeting this mechanism for arthritis.

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MMPIs in Clinical Development for Cancer

Compound	Company	Comments	Phase
Marimistat	British Biotechnology/ Schering Plough	Broad spectrum, dose limiting toxicity. Activity seen in gastric cancer, but negative results in pancreatic.	III
Prinomastat	Agouron/ Warner Lambert/ Pfizer	Moderate gelatinase selectivity, dose limiting toxicity. May be dosing sub-optimally to avoid toxicity. Efficacy data not available.	III
BMS 275291	BMS	Broad spectrum, joint effects seen in Phase I studies.	II

Bayer recently dropped development of BAY 12-9566 due to concerns about potential toxicity. Recent results from a study with marimistat in pancreatic cancer, where adding marimistat to Gemzar resulted in no survival advantage, has led to speculation that MMPis may be more applicable in less aggressive cancer types or earlier stages of the disease. Alternatively, it could be a reflection of the inability to examine higher doses of marimistat due to joint effects.

The joint effects produced by the compounds listed above almost certainly preclude their long-term use, limit compliance and reduce optimal efficacy. Any MMP inhibitor that lacks these side effects will possess a substantial competitive advantage. The musculoskeletal effect produced by marimistat and prinomastat in cancer patients is typically described as arthralgia, myalgia and tendinitis, which occurs predominately in the upper limbs. While mild cases respond to analgesics, interrupting therapy for a period of approximately 2 weeks is necessary when the condition is less well tolerated.

Although Abbott's timing to market is not optimal, the shortcomings of the competitive products provide an opportunity for a compound with an improved SE or efficacy profile. Current animal models seem to predict Abbott's compound is superior to those currently in clinical trials, and has the potential to be best in class.

Product profile

The objective of a product profile at this time in the product's development is to provide a target for the types of attributes that will be required to be commercially successful. This profile is based on market research with oncologists and consultation with opinion leaders. This profile will continue to be refined as more is known about this product's profile, development of competitive products and the market continues to evolve.

	Base	Optimal
Efficacy	ABT-518, alone or in combination with best therapy, provides at least one of the following benefits in at least one solid tumor type: <ul style="list-style-type: none"> - Increased survival - Tumor regression - Improved quality of life - Increased time to tumor/disease progression 	Provides more than one of the efficacy benefits outlined.
Competitive advantage	ABT-518 will need to demonstrate a clinically significant advantage in efficacy (see parameters above) or additive synergistic activity with current/competitive agents or clinically significant advantage in side-effect profile relative to other MMPi agents.	Same
Administration	Convenient administration relative to competitive agents.	Same plus reimbursement in US market.
COGS	A finished cost of goods that is consistent with at least an 80% standard manufacturing margin.	A finished cost of goods that is consistent with at least a 90% standard manufacturing margin.

Marketing overview

Product Usage: Physicians have indicated that they would use MMPi's initially in their more refractory patients, as follow-on or add-on to current best therapy (chemo or surgical). With experience and clinical evidence, they would be willing to use these agents in earlier stages of the disease, where they perceived the greatest benefit to be. The MMPi was regarded as a maintenance therapy to be used in early disease or after primary therapy as a prophylactic process to prevent the spread of malignancy.

Product Benefits/Efficacy: Physicians are looking for improvements in time to tumor progression and prevention of metastases with cytostatic agents. The MMPi mechanism has more recently been implicated as having an even more active role in cancer pathogenesis, from preventing primary tumor growth to anti-angiogenic properties. Positive results from competitive agents, such as marimistat in gastric cancer, provides proof of principle for this mechanism.

Side Effects: The proposed safety profile of MMPi's (excluding joint toxicity) may enhance usage, as the dose limiting toxicity profiles of most of the other available agents has established a much lower hurdle for demonstrating a preferred profile. However, as chronic therapy, MMPi's may have to demonstrate a cleaner profile than cytotoxic agents do to ensure compliance. As the 3rd or 4th MMPi to market, SE hurdles will be even higher for this compound. As a critical Go/No Go decision point, the joint toxicity of this compound will be evaluated in an expanded Phase I multi-dose study.

Dosing: Discovery is currently targeting an oral dosage form. In general, oral therapies are acknowledged by physicians and patients as being more convenient to the patient. Chronic oral dosing may also reduce overall costs, as infusion support products and personnel would not be required, enhancing pharmacoeconomic evidence.

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ABBT246452

COGS: Initial estimates on finished cost of drug suggest that drug costs will not be significant for this compound. With the pricing flexibility in the US market, PPD should be able to get more than 80% margin on this product.

Off-label use: Off label use accounts for between 30-60% of an oncology product's usage. Off-label use is driven by publication of clinical trial results in credible journals, listing in key compendia and/or a peer's experience with the product. Therefore, development spend for off-label use is considerably less than the spend required for regulatory approval of an indication. However, promotion of these off-label uses is limited.

Competition: As the 3rd or 4th MMPi to market, Abbott's compound will need to demonstrate a meaningful clinical advantage over compounds that are in more advanced development. Strict Go/No Go criteria will determine if the MMPi can meet these hurdles. If they cannot be met, the compound will not move forward.

Development/Regulatory: With a new class of compounds, there is not a clearly defined clinical development path or regulatory guidelines for reference. This hurdle is similar for all the competitive products, but increases the overall development risk profile for these agents. However, with several MMPis in late stage development, Abbott can learn from their experience.

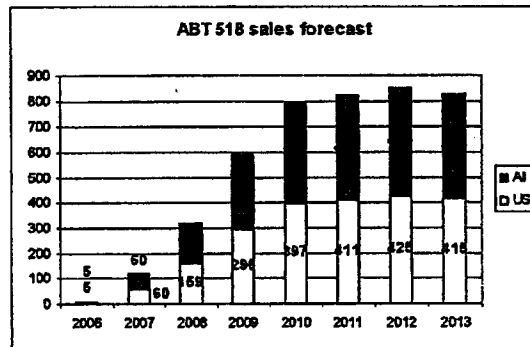
Other Approaches: Other "cytostatic" approaches may present a competitive threat if they are used as substitutes. Due to the complexity of the pathogenesis of cancer, it is more likely that these agents will be used in combinations, but incremental benefits may become more difficult to demonstrate as the number of products and approaches multiply. This will require additional studies, as these other classes become part of standard cancer treatment. However, this threat is not unique to this compound.

Pricing: The treatment of cancer is expensive, so there is the potential for a great deal of pricing flexibility in this market. However, as an oral therapy in the US market, there may be additional downward price pressure for this agent. There is also an increasing emphasis on cost-effectiveness studies that will need to be addressed in the development plan.

Dosing: Discovery is currently targeting an oral dosage form. In general, oral therapies are preferred by physicians and patients because of the convenience to the patient. However, this form may not be the best choice for some people who already have certain digestive system symptoms (vomiting, diarrhea, or severe nausea), cannot swallow liquids or pills, or cannot remember when or how many pills to take. Additionally, in the US market there are several unique factors that currently do not favor oral therapies. Novel oral therapies are not currently reimbursed by Medicare, a significant payer for the oncology patient population. Also, 40-60% of a community oncologist's income is generated through the administration of IV drugs. An oral therapy would not be a source of revenue to the physician.

Financial Projections

A product forecast was developed for the US and ex-US markets.

**Clinical Studies**

Clinical studies across a wide range of solid tumors will be initiated, including but not limited to breast cancer, non small cell lung cancer, ovarian cancer, pancreatic cancer, etc...

Final indications pursued will depend from the results of the phase II studies.

Patent Status

The patent is estimated to expire in August of 2018.

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ABBT246454

Leonard Deposition Exhibit 4

P's Exhibit M

Abbott Portfolio Review

March 7-9, 2001

- Project ABT-518
- Compound Matrix Metalloproteinase Inhibitor
- Presenter Perry Nisen
- Project Team Members
A. Nabulsi (VH), T. Janus (MD), D. D'Amico (CPM)

ABT-518

- ♦ Target indication: Solid tumors.
- ♦ Targeted unmet medical need: Cancer
- ♦ Target product profile vs. current gold standard:



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PLAINTIFFS
EXHIBIT

Leonard 4
11/30/06

ABT-518

◆ Key pre-clinical findings:

- Pharmacology
 - Potent and highly selective (gel-A and gel-B) MMP inhibitor
 - Anti-tumor activity seen in numerous murine cancer models
 - Inhibition of tumor growth is dose dependent
 - Blocks vessel formation in a mouse model of angiogenesis
- Pharmacokinetics / Metabolism in animals
 - Sustained plasma concentrations following single-dose in monkeys
 - Oral bioavailability between 68 and 93% in animals
 - Multiple metabolites are produced after repeat dosing in rats and dogs
- Toxicology
 - No meaningful effects in genotoxicity, cytotoxicity or ligand binding assays
 - No remarkable cardiovascular effects in dogs
 - Stratosis seen in high-dose rats two weeks after drug stopped

ABT-518

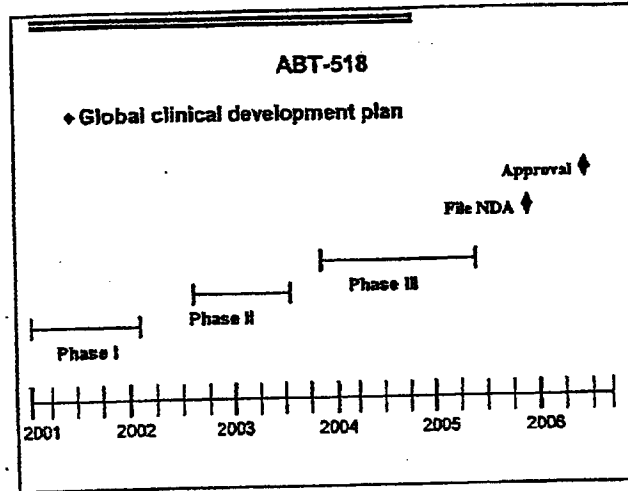
◆ Chemistry and Manufacturing

- Drug substance
 - Six steps from commercial starting materials
 - 3-month turnaround time to manufacture
 - Manufactured at Abbott
- Drug product
 - Neat drug in a capsule (25 and 200 mg) for Phase I
 - Hand-fill or semi-automation at a third party manufacturing facility (Phase I)
 - Formulation development work will begin post Phase II Go/No Go decision

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ABT-518

◆ Clinical development budget

Phase	Funding (\$MM)
Pre-Clinical	5
Phase I	12
Phase II	47
Phase III	78

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ABT-518

◆ Phase I study:

Multiple-dose study in patients with advanced cancer

- Objectives
 - Establish safety profile
 - ✓ Determine the maximum tolerated dose (MTD)
 - Assess PK
 - Determine Phase II dose
- Design
 - 28 days + extension
 - Single-dose of drug administered on Day 1; resume dosing (daily) on Day 4
 - Approximately 40 patients; 3 patients per dose
 - Add 6 or more patients at MTD to collect additional safety information
 - Doses: 25, 50, 100, 200, 400, 800, 1200, 1600, 2000 mg/day

ABT-518

◆ Phase I plan:

IND Study

- Objectives
 - PD-guided Phase II dose selection
 - Long-term safety
- Design
 - Multiple dose escalation study
 - Assess MMP activity in accessible tumors
 - Melanoma
 - Head and Neck Cancer
 - Approximately 20 patients

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ABT-518

◆ Phase II development plans:

- 3 Studies
 - 3 Tumor types as defined by Phase I and animal efficacy
 - 150 patients per study
- Dose finding
- Assess safety issues identified in Phase I
- Thirteen month duration

ABT-518

◆ Phase III plan:

- Demonstrate improvement in survival or TTP in combination with cytotoxic therapies

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ABBT 0013229

Strategic Summary
ABT-518
<p>◆ Key project strengths / positives:</p> <ul style="list-style-type: none"> - Product attributes <ul style="list-style-type: none"> • Highly selective for the inhibition of gelatinases A & B • Very potent • No joint-toxicity expected • Potentially best in class - Technology / Innovation <ul style="list-style-type: none"> • Oral, once-a-day dosing - Time to market <ul style="list-style-type: none"> • Potential for fast-track approval • Launch 2008 - Business franchise strength <ul style="list-style-type: none"> • Comprehensive oncology franchise • Synergies with HFD and ADO - Other relevant points <ul style="list-style-type: none"> • Competitors in class • Non-oncologic indications <ul style="list-style-type: none"> • Multiple sclerosis • Psoriasis refractory • Arthritis

Strategic Summary
ABT-518
<p>◆ Potential issues / Threats / Negatives:</p> <ul style="list-style-type: none"> - Toxicity / side effects <ul style="list-style-type: none"> • Metabolites that may accumulate over time • Potential mechanism-based drug interaction (CYP3A inducer-inhibitor) • Microvascular and macrovascular stenosis in rat study - Manufacturing / cost of goods — No issues anticipated - Efficacy <ul style="list-style-type: none"> • Data released from competitors may cast doubt on class - Clinical recruitment problems <ul style="list-style-type: none"> • Extensive protocol prohibited medications list - Regulatory risk <ul style="list-style-type: none"> • No precedent for cytostatic drug approval • Undefined clinical endpoints • Competitor data may pose additional development hurdles - Technical risks — No issues anticipated - Other relevant issue <ul style="list-style-type: none"> • No good models for selection of dose, regimen and responsive tumor types • PD marker selection

2
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 ABBT 0013230

ABT-518		Strategic Summary
◆ Key decisions:		
- Important upcoming decisions		
• Transition team Go/No Go Phase II - 12/01		
- Proposed budget (2001, and all years to launch)		
Year	R&D per year (\$MM)	
2001	7	
2002	28	
2003	36	
2004	29	
2005	23	
2006	8	

ABT-518		Strategic Summary
◆ Key decisions:		
- Evaluate safety at multiple doses and dose regimens		
- Dose and regimen selection for Phase II		
- Tumor type selection for Phase II		
- Clinical trial design to demonstrate efficacy		

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ABT-518		Strategic Summary
• Proposed action plans		
- Manufacturing		
• Initiate formulation work post Phase II Go/No Go		
- Nonclinical		
• Additional toxicology and metabolism studies are underway to explore the CYP3A and plasma issues		
- Clinical		
• Measure metabolites in Phase I		
• Assess bioactivity via PD markers in Phase I		
• Hold a Pre-IND meeting with the FDA to discuss endpoints		
- Contingency plan		
• Pursue alternative indications		
- Multiple sclerosis		
- Proliferative retinopathy		
- Arthritis		

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ABBT 0013232

Leonard Deposition Exhibit 5

P's Exhibit Y



payment.doc

----- Forwarded by Philip M Deemer/LAKE/HPD/ABBOTT on 12/01/03 02:20 PM -----

Philip M Deemer
03/16/01 11:17 AMTo: Joyce L Davault/LAKE/CORP/ABBOTT@ABBOTT
cc:
Subject: For overhead

John Hancock Executive Summary.c

----- Forwarded by Philip M Deemer/LAKE/HPD/ABBOTT on 12/01/03 02:20 PM -----

Philip M Deemer
03/19/01 11:29 AMTo: John M Leonard/LAKE/PPRD/ABBOTT
cc:
Subject: Re: Hancock [E]

Here is the Executive Summary. If you want the whole contract let me know.



John Hancock Executive Summary.c

John M Leonard

John M Leonard
03/19/01 10:33 AMTo: Philip M Deemer/LAKE/CORP/ABBOTT@ABBOTT
cc:
Subject: Hancock

P: Can you send me some kind of summary of what actually is in the final Hancock contract?

J

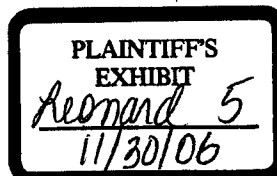
----- Forwarded by Philip M Deemer/LAKE/HPD/ABBOTT on 12/01/03 02:20 PM -----

Philip M Deemer
03/20/01 09:53 AMTo: Perry D Nisen/LAKE/PPRD/ABBOTT@ABBOTT
cc:
Subject: Hancock and Alcon

You probably heard that Hancock was signed last week: \$214,000,000 over 4 years! A long time coming but finally done. We had a little scare at the end when it looked like 518 was being slowed down which could have been the deathnell to the deal. I worked with John to protest that and I understand it is back on track.

On another matter, Alcon called me looking for 2g of 839. We don't need to work with them if there is no/little synergy. I told them I thought it would be difficult to give them that amount at this time but that I would check with you.

Perry, We should catch up with one another before too long.

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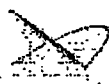
Best regards.

----- Forwarded by Philip M Deemer/LAKE/HPD/ABBOTT on 12/01/03 02:20 PM -----

Philip M Deemer To: Perry D Nisen/LAKE/PPRD/ABBOTT
03/22/01 03:34 PM cc:
Subject: Re: Hancock and Alcon

Perry, thank you for your note. I'm sorry about your sister. I don't want to bother you until you get back from things and vacation but perhaps we could sit down then and catch up. I'm off to Hawaii for a break with my dad and Diane. Best regards to you, Amy and family.

Perry D Nisen



Perry D Nisen To: Philip M Deemer/LAKE/CORP/ABBOTT@ABBOTT
03/21/01 10:30 AM cc:
Subject: Re: Hancock and Alcon

Phil

Mega mazal tov! You are the most tenacious guy I know- you deserve a new car not just a pen. I know all about the 518 debacle (I tell you more over the phone). Since we killed 839 (this was the FTI) I have no objection to sending them some (talk to Saul). There is much I would like to discuss with you. I'm in LA (my sister is quite ill), then if she is stable, to Worcester tonight, then Boston, then return Fri night, but out all next week (school break- vacation).

My cell phone is 847 682 7188. I hope you and Diane are well- haven't spoken to you in ages. We need a f/u mtg with Eisai- Azmi has the clinical brochure and protocols- you may want to send those
pn

From: Philip M Deemer on 03/20/2001 09:53 AM

From: Philip M Deemer on 03/20/2001 09:53 AM
To: Perry D Nisen/LAKE/PPRD/ABBOTT@ABBOTT
cc:
Subject: Hancock and Alcon

You probably heard that Hancock was signed last week: \$214,000,000 over 4 years! A long time coming but finally done. We had a little scare at the end when it looked like 518 was being slowed down which could have been the deathnell to the deal. I worked with John to protest that and I understand it is back on track.

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Best regards.

ABBT 0004508
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— Forwarded by Philip M Deemer/LAKE/HPD/ABBOTT on 12/01/03 02:20 PM —

Philip M Deemer
03/23/01 11:25 AM

To: Nadine Packard/LAKE/PPD/ABBOTT@ABBOTT
cc: Harriet A Mitchell/LAKE/CORP/ABBOTT@ABBOTT
Subject: Hancock Executive Summary

Arthur wanted this executive summary right away so I am sending it to you so you can print it for him. TY

Phil



John Hancock Executive Summary.c

ABBT 0004509
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Leonard Deposition Exhibit 7

P's Exhibit AE

Paige
Gjelen / LAKE / PPRD / AB
BOTT
03/22/2001 02:26 PM
To MMPI Team
cc MMPI cc
bcc
Subject MMPI Working Group Meeting Minutes: 3/8/01

Attached are the meeting minutes and overheads from the 3/8/01 MMPI Working Group Meeting.



3.8.01 Minutes.doc

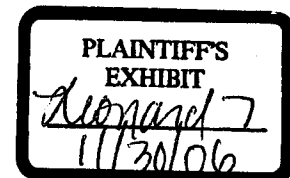


Tox 030801A.xls Tox 030801B.doc PARD 030801.doc

Paige

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ABBT300130



MMPI WORKING GROUP MEETING MINUTES

3/8/01

Objective: Overall Project UpdateClinical Update*Azmi Nabulsi & Diane**D'Amico*

- A brief summary of the Leiden Portfolio Review held 3/7/01 – 3/9/01 was presented. Questions were raised regarding ABT-518 since several competitor MMPi's have been discontinued. We will proceed with the phase I trial. Pre-clinically our compound differs from the competition. In addition, the competitors may have dosed too low, may not have selected the proper tumor stages, and skipped Phase II development.
- The two M00-235 sites were initiated in February. Drug was shipped to both sites and the first patient is expected 3/12/01.

Toxicology Review*Lise**Loberg*

- An update of the two current toxicology studies was presented (see attached slides – Tox 030801A.xls and Tox 030801B.doc)
- Preliminary results from the three-month oral toxicity study in rats were discussed. Changes were seen in the high dose group (300 mg/kg) including decreased body weight, decreased food intake, dehydration and alopecia.
- The first three-month necropsy is planned for 4/10/01.
- The in-life phase of the six-week study has been completed. The process of integrating the mitochondrial function results with clinical pathology and histopathology has been initiated.

PK*Tawakol El-Shourbagy*

- The PK method validation process at Abbott is complete. NKI has not completed their PK method validation process to date. A teleconference will be scheduled within the next few days to determine the status of the PK method validation process at NKI.
- With the PK method validation complete, internal efforts will be directed towards finishing re-analysis of metabolites from toxicology studies conducted last fall; this work is needed for the IND.

PARD*John Cannon*

- An update of clinical supplies was presented (see attached slides – PARD 030801.doc).
- The first 200mg capsule campaign was completed by MDS Pharma Services in Tampa FL. A lower than expected yield rate of 73% resulted in the production of 4,870 acceptable capsules, of which 4,140 capsules will be sent for clinical supply. The low yield rate may be due in part to the larger than expected standard deviation variation for the empty capsules and to the process itself. PARD is looking into the exact cause(s).
- The rejected capsules and recovered bulk drug (deemed experimental) will be used for formulation and process development work. A rework step can be added to future runs to improve yield.

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ABBT300143

MMPI WORKING GROUP MEETING MINUTES

3/8/01

- The next 200mg capsule campaign is planned for June (10,000 capsules, 2 kg bulk drug). Based on the Phase I study in the Netherlands and the IND study design, the possibility of alternate capsule size (i.e., 50 or 100mg) has been discussed. PARD needs a 12-week lead-time from the time of dosing if the capsule size changes from the originally planned 200mg.
- The six-month stability data on 25mg capsules stored in bottles at 40C/75% RH showed some pitting (etiology unknown). At this time, there were no concerns with capsules stored at room temperature.

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ABBT300144

**MMPI Working Group Toxicology Update
February 8, 2001**

**1. Three-month oral toxicity study of Abbott-291518
in rats (with a one-month recovery period)**

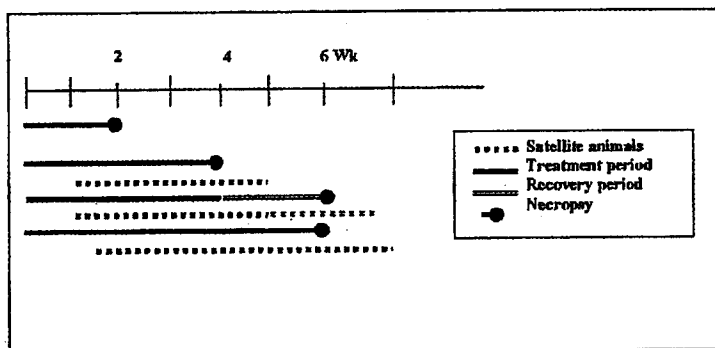
15 rats/sex/dose group (5 satellite rats/sex/dose group)
0, 10, 100 and 300/200* mg/kg/day

*On Study Day 10, the high dosage was reduced from 300
to 200 mg/kg/day due to persistent and substantial decrease
in body weight.

**2. Six-week oral hepatotoxicity study of Abbott-
291518 in rats**

5 rats/sex/treatment group (8 satellite rats/sex/dose
group)

0, 10, 100 and 400 mg/kg/day



ABT-518 Clinical supplies: update

Neat drug in capsule, 200 mg:

- First manufacturing campaign for 6700 capsules at MDS Pharma Services (Tampa FL) completed.
- Yield from Feton encapsulation process was 75% (vs. 95% seen in the feasibility trial); investigation is in progress. The filling process is still largely done by hand and could be subject to such variability due to the large number of operations (100 capsules/operation).
- 4140 capsules to be delivered to 87C for clinical supply.
- 350 grams of bulk drug will be recovered from rejected capsules and used for formulation development work (experimental).

Future 2001 campaigns: including capsules for IND:

- Next campaign, up to 10,000 capsules (2 kg bulk drug) targeted for June; probably will be at MDS again because of resources at IDC.
- Can incorporate a rework step to improve yield.
- Option of manufacturing a 50 or 100 mg / capsule batch is being examined; would require a smaller capsule size if Feton is used.

Stability update:

- 6 month samples of 25 mg capsules stored at 40C/75% RH
some pitting of capsules. Reaction of drug and moisture
with gelatin?
- No concern at room temperature.

Phase II supplies for 2002:

- Will require a "real" formulation (simple, but capable of
automation).
- Development work may have to begin later in 2001; a plan
will be put together by 4/01.

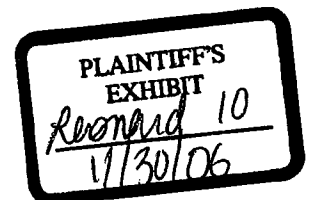
Leonard Deposition Exhibit 10

P's Exhibit KY

From: Lynn C. Klotz [LynnKlotz@compuserve.com]
Sent: Friday, July 28, 2000 10:55 AM
To: Blewitt, Stephen
Subject: Abbott interview writeup

See attached. Overall, most questions were answered satisfactorily--certainly no indication of any deception on Abbott's part. Only one question needs following up, the patent question on ABT-594. Let's talk to see where we go from here, and to discuss the format of the final report.

-- Lynn



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JH 002973

File: interview-abbott

Telephone Interview with Abbott, Conducted by L. Klotz (consultant) and S. Blewitt.

Representing Abbott:

John Leonard, Vice President of Development
Phil _____, Corporate Licensing
Steve Cohen, Controller

[Steve, do you have full names and formal titles for the Abbott participants?]

Almost all answers were provided by John Leonard, as the other two Abbott participants were not scientists and this was a technically oriented interview. Interviewer questions and comments are in italics, Abbotts response in normal type.

ABT-773, ketolide antibiotic for bacteria resistant to antibiotics

To attain a \$1 billion market for a ketolide antibiotic as Aventis predicts (and you also predict), one of the experts we interviewed thought that two things must happen. It must unseat erythromycin, and it must out compete the new fluoroquinolones which are going after the same market. Do you agree with that assessment? If so, how do you see the marketing develop for ABT-773?

Erythromycin was unseated a decade ago, the erythromycin derivative zitromax has \$600 to \$700 US sales and over \$1 billion worldwide. It has 15% market share [*of the derivative market?*].

[He mentioned a few other big sellers, from which it might be concluded that there is a very big total market in which Abbott could achieve a significant market share.]

Fluoroquinolones in the past were used for urinary tract infections, but their marketers are trying to move into the respiratory infection market.

Ketolides are related to macrolides, for which several resistance mechanisms exist. Do you expect resistance to develop rapidly from some of the minor macrolide resistance mechanisms, even though ketolides have been designed to circumvent the major efflux and ribosomal methylation mechanisms?

In the US, efflux is the major mechanism of resistance. I believe in Japan the ribosomal mechanism may be important too. ABT-773 was originally designed and synthesized to avoid efflux. It has demonstrated efficacy on normally antibiotic resistant cells. We are about to enter Phase III trials.

One expert stated that ketolides have a limited range of bacterial-species activity, which will

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probably limit their usefulness to respiratory infections. While respiratory infections (sinusitis, bronchitis and pneumonia) are a very large market, do your market estimates include other large markets? If so, why do you think ABT-773 can serve those other markets?

ABT-773 was designed first and foremost for respiratory indications.

Your Phase II clinical data indicates a 92% effectiveness (overall eradication) against H. Influenzae. How does this compare to erythromycin? If this indicates that ABT-773 is more effective than erythromycin against H. Influenzae, how do you see that affecting market size? Can you break down the increase in market for us.

Very early on we specifically designed our clinical trials to look at *H. Influenzae*, "which sets the bar" for these antibiotics. ABT-773 is as good or maybe better, but the study was small.

Do you see a competitive threat from the new peptide antibiotics such as Daptinomycin?

They are low on our radar screen, because they are IV administered. ABT-773 is for ambulatory patients, who have a cough, a stuffy nose. The IV administered antibiotics are for hospital use. We are developing an IV form of ABT-774, to compete in that market, but the market is small, and we haven't really talked too much about this.

ABT-594, cholinergic channel modulator for diabetic neuropathic pain

Experts in neuropathic pain point to pregabalin (Parke-Davis, Phase III trials) as being especially promising, because it works as well as gabapentin and is safe. How does ABT-924 stack up against pregabalin? Pregabalin will likely finish clinical trials and be approved (if it is approved) before ABT-924. Although measures have been developed, pain relief is subjective, so demonstrating to the FDA that ABT-594 is more efficacious than gabapentin may be difficult. Could the difficulty of providing convincing statistics prevent the approval of ABT-924?

We haven't compared the two drugs head-to-head, but from what we see in the pregabalin literature, we believe our drug is good. I doubt that the FDA would use pregabalin as a standard for approval. In the neuropathic pain area, there are no standards. The last drug was approved 40(?) years ago. We see no approval risk for ABT-594 from pregabalin. Also ABT-594 works through a different mechanism. There is a great need for drugs in the neuropathic pain area.

From your descriptive memorandum, ABT-594 appears to have a therapeutic window of only two to three. Is this small therapeutic window acceptable? Has the FDA approved neuropathic pain relievers with such a low therapeutic window?

Aspirin has a therapeutic window of only ten. For ABT-594, maybe we will be able to get a theoretical window greater than five. When we give patients the upper-limit dose, the side effects aren't dangerous: headache, vomiting. These minor side effects appear to go away over time.

A Merck study claims that in rats "ABT-594 did not cause rotarod impairment at antinociceptive doses but did cause hypothermia and life-threatening adverse effects including seizures." This study also says its results suggest "ABT-594 has nicotine-like dependence liability....These findings indicate that the acute safety profile of ABT-594 is not significantly improved over other nicotinic analgesics." Also, Novartis finds in rats that "ABT-594 dose-dependently increased tail flick latencies but only at doses that also disrupted performance in the rotarod test" Novartis also claims "In all tests, (+)-epibatidine was significantly more potent than ABT-594." According to Abbott, ABT-594 is as efficacious as (+)-epibatidine, which is too toxic for use. How do you explain the differences between your findings in rodents and humans and the Merck and Novartis findings in rodents?

Someone called my attention to the Merck study, I don't think I've seen the Novartis one. However, in clinical studies I would trade five million rats for a hundred people.

Why are Merck and Novartis taking "pot shots" at you?

I think Merck and Novartis are using us as a standard. We are the only drug to compare with. Merck bought Sybia, the company which has rights to many of the receptors like the one we are targeting.

Is ABT-594 clear of the Sybia's patents?

ABT-594 was prior to the Sybia/Merck arrangement. Future products must avoid Sybia's rights.

[Note: this did not actually answer whether Abbott has an invention prior to Sybia, or if Sybia's patents may cover the receptor for Abbott's drug. We should clarify this.]

In an Abbott year 2000 study in rats, ABT-627 (the advanced prostate cancer cytostatic and pain drug) was examined for diabetic neuropathy. How does the promise of ABT-627 compare to ABT-594 for neuropathic pain? Are the two drugs structurally related? Is Abbott heading toward clinical trials with ABT-627 for neuropathic pain?

Yes, we have looked at ABT-627 as an analgesic, it has limited value for pain, so we won't pursue it.

ABT-627 also might be used to treat cardiovascular disease. We don't serve that market, so we won't pursue that indication for business reasons.

ABT-980, alpha 1a adrenoceptor antagonist for BPH

In a Chinese literature study comparing selective (tamsulosin, Flomax) and non-selective (terazosin) alpha 1-adrenoceptor antagonists, tamsulosin showed better results in maximum urinary flow rate (Qmax), and average urinary flow rate (AFR). But the results, in our naive opinion, were not dramatically different. For example, AFR increased 37.5% for tamsulosin and

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JH 002976

25.8% for Flomax. I know these drugs sell well, but I am not sure why.

In our human trials we look at flow, and we look at symptoms. Treating the symptoms is important. For example does the bladder empty completely, is urgency to urinate reduced or eliminated.

We have completed Phase II, clinical trials and are about to enter Phase III. Our data so far, show that ABT-980 is virtually super imposable on Flomax, maybe we are slightly better in a few areas.

At what point does the FDA say, OK we have a number of products on the market which are not improvements over the previous ones, we won't approve the next one because patients don't need another similar product?

This is an incremental product, a lot of what our industry does is incremental products. So it becomes a marketing and pricing issue. The FDA doesn't make decisions based on the number of products already on the market. In Europe, where prices are controlled, if a product is a me-too product, it can enter the market but at a lower price.

One literature study refers to a patient population that is responsive to alpha1-adrenoceptor antagonists. Does this mean there is a subgroup of patients that don't respond to BPH drugs targeted to alpha1-adrenoceptor? How big is this subgroup?

I can't answer that; on one has carried out pharmacogenetic studies. The subgroup referred to could be those whose prostate is so big, nothing short of surgery will help them.

A-254751, tubulin colchicine-site binding drug to inhibit microtubule formation for advanced cancers

One expert said, of the number of colchicine-site binding agents in preclinical and in clinical trials, combretastatin-A4 (Oxigene, Phase I trails) stands out. He said it is receiving a lot of attention because it is also an antivascular agent. How does A-254751 stack up against combrestatin?

I don't know.

A strikingly large number of colchicine-site drugs have been abandoned in clinical trials. One expert claims the older colchicine-binding drugs failed before they are too toxic. More specifically, the older drugs failed for pharmacokinetic reasons: mainly too long half-lives in the body. He further stated: what one wants are colchicine-binding drugs that get into cells quickly, do their job, and are eliminated from the body quickly. Do you agree with this assessment? What are the pharmacokinetics of A-254751? How does the drug escape MDR?

I can't give you the pharmacokinetic data from memory.

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Could we look at it?

Yes, I can get it for you.

[Since A-254751 is in early stage clinical trials, the data may give us some insight about its prospects. But I am already rating this drug as only having a fair chance of FDA approval based on the fate of the other colchicine-site binding agents. I don't see that the data can change that opinion, so I withdrew the request to see it.]

We don't know how the drug escapes the MDR mechanism.

How does A-254751 compare to other colchicine-site binding agents regarding toxicity?

We think the window is pretty good compared to others.

Cytostatic drugs (except for ABT-627, the endothelin ET-1 antagonist)

One literature review indicated that approximately thirty angiostatic agents are undergoing clinical trials, with another fifty agents in preclinical testing. This is a crowded field. While Abbott's approaches are clearly competitive, how can Abbott achieve a large market share given the large number of competitors in the cytostatic area in general?

I agree that for cytostatic drugs in general their may be 50 to 200 in testing. To get the market lead, get one that works. In this business, there are a number of people who start things, many more than the ones who finish.

One expert tells us that so far the FDA has not wavered from the strict position of improved survival as the criterion for cancer drug approval. This would include longer survival and improved quality of life. They have not yet approved any drug for slower disease progression. Since cytostatic therapies don't kill tumor cells, the use of time to progression of disease seems to be the necessary clinical trials measure. What are the problems with this measure? Do you think the difficulty of measuring time to progression, lack of statistically significant evidence of longer survival, and difficulty in determining improved quality-of-life will prolong clinical trials or cause some drugs to fail to get FDA approval? How serious an issue is this?

You set this question up too starkly. Clearly drugs that make people to live longer, as long as they maintain a quality of life, are likely to be approved. With ABT-627, we are working with the FDA to determine what is a meaningful clinical progression. We are working with the FDA every step of the way.

For any of your cytostatic drugs, have you any data for cost utility = (long-term-cost)/(quality-life-years-saved)? In particular, if there are side-effects, quality-life-years saved may be much less than simply life-years-saved, and cost-utility may be high.

We haven't done cost-utility precisely, but we compare favorably with other products—for

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JH 002978

example, ABT-627 compares favorably with Luprolide, a chemical castration drug with sales of \$800 million. Also, Luprolide is very expensive.

In this regard, metalloproteinase inhibitors are particularly worrisome. One of our experts stated that the metalloproteinase inhibitor BB-94 has "underwhelming" efficacy. It is toxic and causes joint problems. Additionally, one literature study finds that the metalloproteinase inhibitor Marimastat had no survival advantage when compared to chemotherapy with gemcitabine in advanced pancreatic cancer, and Abbott states that Marimastat has dose-limiting joint side-effects. To play devil's advocate, you could argue: Why should the FDA approve a drug that does not prolong a patient's life and at the same time inflicts pain? Could failure for approval of Marimastat make the approval barriers higher for follow-on drugs? What evidence do you have that gelatinase inhibitors like ABT-518 might not have the same FDA approval concerns?

British Biotech was first with Marimastat, so it has the problems of being first. One thing Abbott has learned from Marimastat is that it is not selective enough. Abbott's metalloproteinase inhibitor avoids blocking a particular enzyme that is needed to keep joints clear. Abbott's drug does not create what we call "frozen shoulder." There is a good animal model that we use for frozen shoulder.

ABT-627, the endothelin ET-1 antagonist

Abbott's internal memorandum describes ABT-627 as a potent vasoconstrictor. Abbott indicated in its internal memorandum that the mechanism of action in prostate cancer wasn't yet known. Additionally, one of our experts said that reducing blood supply to tumor cells was likely not the mechanism by which ABT-627 delays prostate cancer progression, since the cancer metastasize to bone and is slow growing both indicating there is less need for a good blood supply. What are your latest thoughts about mechanism of action? A competitor who has a better knowledge of mechanism may be in good position to develop a superior drug.

Yes, we agree that the mechanism of action for metastacized prostate cancer is not vasoconstriction. We do have knowledge about mechanism for prostate cancer.

[The interview ended here because Steve Cohen had an important meeting to attend. There was little need for additional questions on ABT-627 as well.]

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Leonard Deposition Exhibit 13

P's Exhibit CT

September 2000
ABT-594 Project Status Report

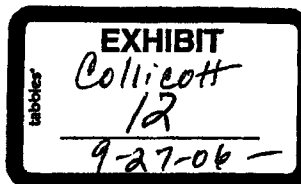
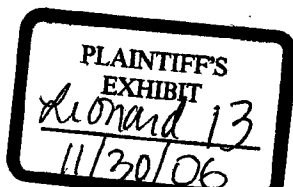
Key Issues/Decisions/Events

Area	Issue/Decision/Event	Progress
Venture	Extension of enrollment for Phase IIB Neuropathic Pain through 03/01	<ul style="list-style-type: none"> Sites have been notified and contract revisions in process Budget impact is under evaluation - complete in October
PARD	75 µg HGC will be made for Phase IIB. Higher capsule strengths may be required.	<p>Hard gelatin capsule (HGC) has been chosen as the Phase IIB/Ill formulation. Phase Ill formulation process optimization started 5/00. Capsule strengths of 75 and 150 mcg have tentatively been chosen for Phase Ill studies.</p> <p>A very low EEL (employee exposure level) of 1 mcg/m3 has been set for ABT-594; however, the proposed formulation/process decreases the potential for employee exposure, allowing PPD's Puerto Rico facility (AHP) to be the site of production. In order to test safety systems, manufacture of a capsule batch in the AHP high potency drug module was completed 8/00. Measurements of employee exposures indicated the need for some modification of the encapsulation equipment/process, and observation of material transfer points indicated the need for some improvement before scale-up activities are performed. More extensive engineering controls will be required for commercialization of this product.</p>
SPD	<p>We are at risk for possible increases in the cost of drug substance because we are dependent on other vendors to manufacture ABT-594 drug substance.</p> <p>Toxicology has recommended an impurity limit for mesylate needs to be set below the level of detection (LOD 0.002 & LOQ 0.005). A recrystallization procedure will be needed. Additional process work may be needed depending upon the outcome of the recrystallization process.</p>	<p>Abbott cannot manufacture highly potent compounds. SPD has identified several potential vendors for the drug substance: Sico, Chemsyn and Celalytica. Chemsyn has been selected as the manufacturer of the bulk drug substance.</p> <p>Three registration lots totaling 16 Kg have been completed at Chemsyn.</p> <p>A meeting to discuss selling the mesylate impurity limit was held on September 30, 1999. A specification set below the current limit of detection was advised by toxicology.</p> <p>CMC technical committee meeting held 1/6/00 to discuss mesylate specifications. Recommendations made. Mesylate specification at target; not more than 0.005% will be incorporated into Standard Control Procedure.</p> <p>Development of a recrystallization process of the current method has started. This should be incorporated into the process for the registration lots.</p> <p>All 3 registration lots recrystallized. All below 0.005% mesylate.</p> <p>Will begin testing for release and stability initiation of the 3 NDA lots of drug substance.</p> <p>Replacement Step 4 (Mitsunobu) chemical synthesis to eliminate mesylate going well in lab. Continuing analytical scrutiny for low level impurities in final drug substance. Determination to proceed with implementation of replacement Step 4 under evaluation.</p>

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September 2000
ABT-594 Project Status Report

Project Cost Summary - September						
\$000's Activity	Cumulative through 1999	YTD Actual	Projected Year-end	Current Funded Year-end	Variance	Cumulative to NDA
Clinical Program	22.9	5.3	7.1	7.9	.8	157.1
CMC (PARC & SPD)	13.0	2.5	3.1	2.6	-.5	27.6
Drug Safety	8.7	2.5	3.2	2.4	-.8	18.3
Other Support Costs	0.7	.6	1.0	1.5	.5	12.2
Total	50.5	10.9	14.4	14.4	0.0	215.2

File NDA = 5/2003

* Clinical program = grants, data mgmt/stats, venture management, drug supplies

** Other Support Costs = Regulatory Affairs, RQA, Medical Services, Phase 1, RIC, Int'l MP, Invest, Drug QA, Discovery, Project Services

Protocol # - Study Name	Clinical Study Progress		Total R/OSS \$000	Total Target Patients	Current Enrollment
	Start (1 st Patient Dosed)	End (Last CRF In House)			
M99-114 – A Randomized, Double-Blind, Placebo-Controlled Comparison of the Safety and Efficacy of ABT-594 to Placebo in Subjects with Painful Diabetic Polyneuropathy	04/00	04/01	3,000	320	180

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September 2000
ABT-594 Project Status Report

Business Rationale

Date: September 2000
Franchise: Neuroscience
Venture: Analgesia

ABT #: ABT-594
Trade & Generic Name: TBD, TBD
Mechanism of Action: Cholinergic Channel Modulator (ChCM)

Indications: Neuropathic Pain
Chronic Pain (publication only)

Product Profile				Market Forecast			
Attribute	Date Defined	Probability*	Conform Status	Share Impact	PPCC/DDC 12/1996*	Plan as of 6/1998*	Current Revised 10/1999**
Not scheduled	12/1996	High	1Q04	High	10/2010 (est.)	10/2010 (est.)	10/2010 (est.)
Chronic nociceptive pain efficacy	10/1999	Medium	2Q01	High	12/1999 (acute)	12/2001	5/2003
Neuropathic pain claim	6/1999	Medium	2Q01	High	6/2001 (chronic)	12/2001 - Eur	Update Pending
General pain claim	12/1996	N/A	N/A	High	Same as above - Eur	12/2003 - Jpn	5/2004
Moderate to moderately severe pain	9/1998	Medium	1Q03	High	N/A - Jpn	6/2003	Update Pending
No tolerance/dependence or withdrawal	9/1998	High	2Q01	High	12/2002 (chronic)	12/2003 - Eur	Update Pending
Very few abnormal LFTs	6/1999	Medium	2Q01	High	Same as above - Eur	9/20/2004 - Jpn	20%
Low nausea/vomiting at effective dose	9/1998	High	2Q01/1Q03	High	N/A - Jpn	5% (Rx)	(Neuropathic pain)
Other safety OK	9/1998	High	2Q01/1Q03	High	6.8% (patients)		10%
No differential efficacy (nicotine users vs. non users)	9/1998	Medium	2Q01/1Q03	Medium	5.4% (patients)	5% (patients)	(Persistent Chronic Pain)
No differential side effect profile (nicotine users vs. non users)	9/1998	N/A	N/A	Medium	\$285	\$818	5% patients
No rehabilitation of cravings in ex-nicotine users	6/1999	Low	4Q01	Medium	\$308	\$310	\$387
Onset of action comparable to other therapies for chronic nociceptive pain	6/1999	N/A	N/A	Medium	\$338	\$305	Update Pending
Onset of action comparable to other therapies for neuropathic pain	6/1999	N/A	N/A	Medium	\$412	\$813	Update Pending
BID dosing	6/1999	High	2Q01	High	Avg. daily dose	200 mcg	150 mcg
No major drug interactions	12/1996	High	1Q03	Medium	Target Drug Cost/Mg at Launch	\$2,500	\$2,500
Titration of 2-5 days duration is required to minimize nausea and vomiting at effective dose.	9/1999	Medium	1Q00	High	SMM at Launch	97.2%	98.5%
					SMM at Year 5		

* Forecast based on general pain target indication

** Forecast based on neuropathic pain indication and published study in chronic pain

Probability Key:
High = 70-100%
Medium = 30-69%
Low = 0-29%

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September 2000
ABT-594 Project Status Report

Project Overview

Metrics Dates		Description	Date
Plan	Actual		
DDC Meeting	12/1996 (PPCC)		
Start of first GLP animal tox study	2/1997		
First dose in human (beg. Phase I)	7/1997		
First dose in patient (beg. Phase II)	7/1998		
First dose in Phase III	2/2002 (est.)		
Last Patient's Last Visit	4/2003 (est.)		
NDA Filing	9/2003 (est.)		
NDA Approval	9/2004 (est.)		
Europe (EMEA) Filing	9/2003 (est.)		
Europe (EMEA) Approval	TBD		
Japan Filing	4/2004 (est.)		
Japan Approval	TBD		

PARD

Activity	Plan 6/1999	Current Revised 6/00	Actual
Phase I Formulation (PIB)*	7/1997	7/1997	7/1997
Clinical Supplies (PIB) for Molar Extraction	7/1998	7/1998	7/1998
Phase II Formulation (SEC) for IND	7/1998	7/1998	7/1998
Clinical Supplies (SEC) Shipped (Osteoarthritis, Surgery, Neuropathy)	10/1998	10/1998	10/1998
Phase IIb / Formulation (HGC) for Bio Study	3/1999	3/1999	3/1999
Phase III Clinical Supplies Manufactured	9/1999	6/2001	TBD
NDA Lots (3) Completed	6/2000	12/2001	TBD
Completion of 1 Year Stability for NDA	7/2001	2/2003	TBD
Formulation Peer Review	10/2001	TBD	TBD

* Performed by IDC

CAPD

Drug Substance Source/Lot #	KG	Plan 6/1999	Actual Date	Projected Cost/kg*
D-45L	0.3 KG	3/1997	3/1997	\$ 200,000
CAPD	5.6 KG	3/1997	3/1997	\$ 175,000
SICOR	14.9 KG	2/1998	2/1998	\$ 40,000
SICOR/CAPD	2.5 KG	8/1998	8/1998	\$ 40,000
Chemsyn Pilot Lot	1.0 KG	5/1999	5/1999	\$ 29,700
Chemsyn Mfg. Lot	10.0 KG	10/1999	Not manufactured	\$ 29,700
Chemsyn NDA Lot #1	4.85 KG	10/1999	On Test	\$ 29,700
Chemsyn NDA Lot #2	4.80 KG	10/1999	On Test	\$ 29,700
Chemsyn NDA Lot #3	5.45 KG	10/1999	On Test	\$ 29,700

* Target cost of drug substance at launch is \$20,000/kg (Tox/late Salt)

Toxicology

Toxicology Activity	Plan Start 1999	Actual Start Date	Report Completed
Gene Toxicology	2/1997	9/1996	8/1997
Acute Studies	3/1997	4/1997	8/1997
1 Month Rat/Monkey	2/1997	2/1997	11/1997
3 Month Rat/Monkey	7/1997	6/1997	8/1998
3 Month Mouse MTD	10/1997	6/1997	10/1998
SEG I and SEG II	10/1997	7/1997	7/1998
SEG III Rat (post natal development)	--	1/1999	Ongoing
6 Month Rat	1/1998	3/1998	7/1999
1 Year Monkey	6/1998	6/1998	3/2000
Cardiogenicity (2 yr.) Rat	12/1998	8/1998	Ongoing
Cardiogenicity (2 yr.) Mouse	12/1998	11/1998	Ongoing

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**September 2000
ABT-594 Project Status Report**

Clinical Study Progress

Protocol:

M99-114 – A Randomized, Double-Blind, Placebo-Controlled Comparison of the Safety and Efficacy of ABT-594 to Placebo in Subjects with Painful Diabetic Polyneuropathy

Objective:

The objective of this study is to compare the safety and analgesic efficacy of 150 µg, 225 µg, and 300 µg twice daily (BID) of ABT-594 to placebo in subjects who have painful distal symmetric diabetic polyneuropathy.

ABT-594 Doses:

150 µg, 225 µg, and 300 µg twice daily (BID)

Comparator Doses:

Placebo

Target Enrollment:

320

Target Cost:

\$3 MM

Actual Cost:

TBD

Status:

Ongoing – 180 patients randomized as of 9/30

Major Findings:

TBD

D:\771\WP\SR\Sept. 2000\ABT-594 September 2000 MP\SR.doc

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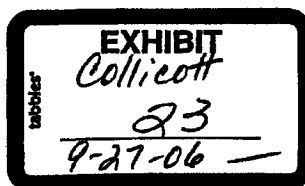
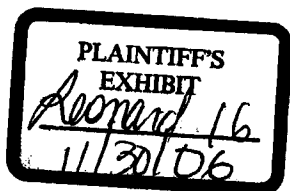
P's Exhibit IH

December 2000 - "Top" Issues

Key Issues/Decisions/Events

Area	Issue/Decision/Event	Progress
Redacted		
ABT-482 Clinical	Phase I single rising dose was completed 12/15/00.	Doses ranging from 50 mg to 1600 mg were administered with no serious adverse events. Urine samples indicate that the drug is available in the urine and that UTI indications can be pursued.
ABT-594	Closing of enrollment on M99-114 as of January 5, 2001	It was agreed in December to close enrollment into M99-114, our Painful Diabetic Neuropathy trial, as of January 5, 2001. This is 2 months ahead of our most recent estimate of March 5, 2001, and will include less than our original target of 320 patients. This acceleration of the study close date was driven by our desire to evaluate the outcome of the study, and an assessment of the statistical power of the study.
ABT-827 NPD	Submitted on 12/1 abstracts for Spring AUA and ASCO annual meetings.	<p>This issue has been reviewed with PARD, SPD, Toxicology, Regulatory and Venture Management. To date, the F¹ impurity has been detected at a level of 0.2% in the drug substance. Tentative identification including molecular structure has been made.</p> <ul style="list-style-type: none"> Due to significant chemistry challenges, the delivery of impurity F¹ to PARD from SPD is delayed. New target date to be determined pending favorable results from current synthesis efforts. PARD Analytical will be testing the F¹ material to confirm identity and match to impurity found in drug substance lot; planned January 2001 <p>When testing is successfully completed, F¹ material will be tested for genotoxicity by Toxicology and for bioavailability by Exploratory Kinetics</p>
ABT-781 PARD	Development of final formulation for Phase I studies completed 12/31.	
ABT-773 NPD	Phase IIIa data will be important predictors of commercial value	Phase IIIa studies to be complete 5/2001. FDA changes to the Phase III protocols creates a

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P's Exhibit R

Philip M Deemer

03/12/2001 03:03 PM

To: sblewitt@jhancock.com@internet
Subject: MMPI Program Update

John Leonard looked at all of the documents one last time in preparation for execution and noted an oversight on one of the Programs. On the ABT-518 program, he noted that Phase I was to have started on December 2000 (4Q2000) but in fact did not start until earlier this month. This pushed the timeline back by a quarter throughout but the launch date is not affected and is actually planned one quarter earlier (2Q06). Steve, as you know the timing of starting some of these earlier compound studies is related to completing this financing and hence the reason this one got pushed back a little.



ABT-518 0301.doc



ABT-518 0301.WK4



ABT-518 0301.xls

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EXHIBIT

Leonard 27
11/30/01

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ABT - 518

Descriptive Memorandum

February 2001

Abbott Laboratories

**ABBT 0004032
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MMPI**Overview**

Abbott's Matrix Metalloproteinase Inhibitor (MMPI) program represents a novel therapeutic class, with the potential to alter the way that cancer is treated by preventing or modifying disease progression and/or metastases. This more "chronic" approach to therapy has the potential to transform cancer into a disease that patients live with, much like the effect of HIV protease inhibitors on patients with AIDS. It also has the potential to expand the cancer market significantly by increasing the average length of treatment and expanding the pool of patients eligible to receive therapy.

The MMPs comprise a family of enzymes that degrade a wide range of matrix protein substrates. High expression of these enzymes occurs in cancer and is associated with the ability of tumors to grow, invade, develop new blood vessels and metastasize.

MMP inhibitors (MMPIs) may suppress the progression of tumors by several mechanisms:

- Suppress invasion/metastasis by blocking the membrane traversal and access to blood/lymphatic vessels
- Blocking the remodeling of extra-cellular matrix in the vicinity of primary tumors to prevent stroma-bound growth factors from stimulating tumor growth
- Blocking angiogenesis by preventing the proliferation and migration of endothelial cells and neovascularization of tumor.

Experimental evidence suggests that gelatinase A and gelatinase B are particularly important in tumor progression, consequently the project team has targeted gelatinase selective inhibitors for the treatment of cancer. Another reason for targeting highly gelatinase selective MMP inhibitors relates to the side effect profile exhibited by broad-spectrum agents like marimastat. Chronic administration of marimastat causes a dose-limiting side-effect characterized by severe joint pain and stiffness. Since these joint effects may be mediated by inhibition of other MMPs like fibroblast collagenase, highly gelatinase selective agents may be efficacious without producing dose-limiting side effects.

The MMP selectivity profile exhibited by ABT-518 distinguishes it from competitor's compounds. ABT-518 possesses sub-nanomolar inhibition potencies versus both gelatinase A and gelatinase B and is substantially more selective for the inhibition of the gelatinases over fibroblast collagenase than marimastat and prinomastat. Despite its high selectivity, ABT-518 demonstrates antitumor activity equal or superior to prinomastat. Inhibition of tumor growth is dose dependent in both syngeneic and xenograft models. ABT-518 is also effective in blocking vessel formation in a mouse model of angiogenesis. ABT-518 is a stable crystalline solid which can be synthesized in six steps (25% overall yield) from commercial starting material.

ABT-518 gives rise to sustained plasma concentrations following single oral dosing in monkeys, dogs and rats. Bioavailabilities range between 68 and 93% depending on formulation and species. Several metabolites are produced after repeated oral dosing of ABT-518, although their relative amounts varies with gender and species.

ABT-518 displays no meaningful effects in genotoxicity, cytotoxicity and ligand binding assays and its cardiovascular effects in dogs are unremarkable. ABT-518 produces no significant toxic effects in rats treated with 100 mg/kg/day over 28 days. Plasma concentrations generated by ABT-518 in these studies are at least 20-fold higher than those necessary to produce efficacy in cancer animal models. ABT-518 is therefore a compelling development candidate with the potential to

demonstrate antitumor effects superior to the MMP inhibitors currently undergoing clinical trials. Phase 1 clinical trials in cancer patients began March 2001.

The market

Currently, cytotoxic agents represent the largest, and fastest growing, class of oncology agents by sales volume. The following chart summarizes the value of the current oncology market.

Global Sales by Market Segment (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est)	CAGR '96-'98
Hormone	4,414	4,784	4,884	5,000	5.2%
Cytotoxic	4,278	5,212	6,268	7,300	21.0%
Adjunctive	3,367	3,651	4,166	4,900	11.2%
Total	12,059	13,647	15,318	17,200	12.7%

Source: Datamonitor

Sales by Region (\$ MM)

	1996 Sales	1997 Sales	1998 Sales	1999 Sales (est)	CAGR '96-'98
US	5,564	6,276	7,422	8,500	15.5%
Ex- US	6,495	7,370	7,896	8,700	10.3%

Source: Datamonitor

Cytostatic agents have the potential to alter the way cancer is treated and presents opportunities for fundamentally new ways of approaching the disease. This cytostatic market does not yet exist, though success of more cytostatic "like" treatments, such as hormonal therapies for prostate and breast cancer, suggest that the market potential for cytostatic agents could be significant.

The ultimate commercial and clinical success of the MMPI will depend on the clinical benefit this product provides in key cancer types compared with current best therapy. These can be benefits provided by dosing this agent in addition to current therapy and/or as an alternative to best therapy, or as a new component of best therapy. All currently available products, including the market leaders such as Taxol, have significant shortcomings in their profiles.

However, as novel therapy, MMPIs will probably be adopted initially as add-on the current chemotherapy. As benefits are proven and clinical experience is gained, these agents may be used in earlier stages of cancer and/or in conjunction with surgery or radiation to prevent the progression of any microscopic disease that remains.

The clinical targets identified for this compound include late stage pancreatic cancer, late stage NSCL cancer (on-label), with late stage ovarian and breast cancer as additional cancer types where efficacy has been demonstrated, but not filed. Other cancer types this compound may be efficacious in include SCL, colorectal, bladder, stomach and prostate. Targets will be refined as we know more about this compound's in-vivo activity.

The following tables summarize the key marketed competitive products by indication (US data only):

Late Stage Breast	
Product	Share
Cyclophosphamide/Cytoxan/BMS	18.7
Doxorubicin/Adriamycin/P&U	17.11
Docetaxel/Taxotere/RPR	16.25
Paclitaxel/Taxol/BMS	16.11
Trastuzumab/Herceptin/Genetech	11.26

Late Stage NSCL	
Product	Share
Carboplatin/Paraplatin/BMS	50.32
Paclitaxel/Taxol/BMS	44.14
Vinorelbine/Navelbine/Glaxo	22.78
Gemcitabine/Gemzar/Lilly	22.14
Cisplatin/Platinol/BMS	11.28

Late Stage Ovarian	
Product	Share
Paclitaxel/Taxol/BMS	47.11
Carboplatin/Paraplatin/BMS	45.42
Topotecan/Hycamtin/SKB	22.54
Dox SL/Doxil/Alza	9.14
Cisplatin/Platinol/BMS	7.58

Late Stage Pancreas	
Product	Share
Gemcitabine/Gemzar/Lilly	78.5
5-FU/Efudex/ICN Pharma	21.0
Leucovorin/	10.7
Cisplatin/Platinol/BMS	4.72

Compounds in Development

The MMP inhibitor field is competitive. More than 30 firms have filed patents claiming small molecule MMP inhibitors over the past 5 years, and several companies have compounds in advanced clinical development. Abbott's compound may be 3rd or 4th to market and will have to demonstrate a competitive advantage to gain the share necessary to support the clinical development of this compound. Companies with compounds in advanced clinical development for the treatment of cancer include Agouron/Warner Lambert/Pfizer, British Biotechnology/Schering Plough and BMS and are listed below. Other companies are targeting this mechanism for arthritis.

MMPis in Clinical Development for Cancer

Compound	Company	Comments	Phase
Marimistat	BritishBiotechnology/ Schering Plough	Broad spectrum, dose limiting toxicity. Activity seen in gastric cancer, but negative results in pancreatic.	III
Prinomastat	Agouron/ Warner Lambert/ Pfizer	Moderate gelatinase selectivity, dose limiting toxicity. May be dosing sub-optimally to avoid toxicity. Efficacy data not available.	III
BMS 275291	BMS	Broad spectrum, joint effects seen in Phase I studies.	II

Bayer recently dropped development of BAY 12-9566 due to concerns about potential toxicity. Recent results from a study with marimistat in pancreatic cancer, where adding marimistat to Gemzar resulted in no survival advantage, has led to speculation that MMPs may be more applicable in less aggressive cancer types or earlier stages of the disease. Alternatively, it could be a reflection of the inability to examine higher doses of marimastat due to joint effects.

The joint effects produced by the compounds listed above almost certainly preclude their long-term use, limit compliance and reduce optimal efficacy. Any MMP inhibitor that lacks these side effects will possess a substantial competitive advantage. The musculoskeletal effect produced by marimastat and prinomastat in cancer patients is typically described as arthralgia, myalgia and tendinitis, which occurs predominately in the upper limbs. While mild cases respond to analgesics, interrupting therapy for a period of approximately 2 weeks is necessary when the condition is less well tolerated.

Although Abbott's timing to market is not optimal, the shortcomings of the competitive products provide an opportunity for a compound with an improved SE or efficacy profile. Current animal models seem to predict Abbott's compound is superior to those currently in clinical trials, and has the potential to be best in class.

Product profile

The objective of a product profile at this time in the product's development is to provide a target for the types of attributes that will be required to be commercially successful. This profile is based on market research with oncologists and consultation with opinion leaders. This profile will continue to be refined as more is known about this product's profile, development of competitive products and the market continues to evolve.

	Base	Optimal
Efficacy	ABT-518, alone or in combination with best therapy, provides at least one of	Provides more than one of the efficacy benefits outlined.

	<p>the following benefits in at least one solid tumor type:</p> <ul style="list-style-type: none"> • Increased survival • Tumor regression • Improved quality of life • Increased time to tumor/disease progression 	
Competitive advantage	ABT-518 will need to demonstrate a clinically significant advantage in efficacy (see parameters above) or additive synergistic activity with current/competitive agents or clinically significant advantage in side-effect profile relative to other MMPi agents.	Same
Administration	Convenient administration relative to competitive agents.	Same plus reimbursement in US market.
COGS	A finished cost of goods that is consistent with at least an 80% standard manufacturing margin.	A finished cost of goods that is consistent with at least a 90% standard manufacturing margin.

Marketing overview

Product Usage: Physicians have indicated that they would use MMPi initially in their more refractory patients, as follow-on or add-on to current best therapy (chemo or surgical). With experience and clinical evidence, they would be willing to use these agents in earlier stages of the disease, where they perceived the greatest benefit to be. The MMPi was regarded as a maintenance therapy to be used in early disease or after primary therapy as a prophylactic process to prevent the spread of malignancy.

Product Benefits/Efficacy: Physicians are looking for improvements in time to tumor progression and prevention of metastases with cytostatic agents. The MMPi mechanism has more recently been implicated as having an even more active role in cancer pathogenesis, from preventing primary tumor growth to anti-angiogenic properties. Positive results from competitive agents, such as marimistat in gastric cancer, provides proof of principle for this mechanism.

Side Effects: The proposed safety profile of MMPi (excluding joint toxicity) may enhance usage, as the dose limiting toxicity profiles of most of the other available agents has established a much lower hurdle for demonstrating a preferred profile. However, as chronic therapy, MMPi may have to demonstrate a cleaner profile than cytotoxic agents do to ensure compliance. As the 3rd or 4th MMPi to market, SE hurdles will be even higher for this compound. As a critical Go/No Go decision point, the joint toxicity of this compound will be evaluated in an expanded Phase I multi-dose study.

Dosing: Discovery is currently targeting an oral dosage form. In general, oral therapies are acknowledged by physicians and patients as being more convenient to the patient. Chronic oral dosing may also reduce overall costs, as infusion support products and personnel would not be required, enhancing pharmacoeconomic evidence.

COGS: Initial estimates on finished cost of drug suggest that drug costs will not be significant for this compound

Off-label use: Off label use accounts for between 30-60% of an oncology product's usage. Off-label use is driven by publication of clinical trial results in credible journals, listing in key compendia and/or a peer's experience with the product. Therefore, development spend for off-label use is considerably less than the spend required for regulatory approval of an indication. However, promotion of these off-label uses is limited.

Competition: As the 3rd or 4th MMPI to market, Abbott's compound will need to demonstrate a meaningful clinical advantage over compounds that are in more advanced development. Strict Go/No Go criteria will determine if the MMPI can meet these hurdles. If they cannot be met, the compound will not move forward.

Development/Regulatory: With a new class of compounds, there is not a clearly defined clinical development path or regulatory guidelines for reference. This hurdle is similar for all the competitive products, but increases the overall development risk profile for these agents. However, with several MMPIs in late stage development, Abbott can learn from their experience.

Other Approaches: Other "cytostatic" approaches may present a competitive threat if they are used as substitutes. Due to the complexity of the pathogenesis of cancer, it is more likely that these agents will be used in combinations, but incremental benefits may become more difficult to demonstrate as the number of products and approaches multiply. This will require additional studies, as these other classes become part of standard cancer treatment. However, this threat is not unique to this compound.

Pricing: The treatment of cancer is expensive, so there is the potential for a great deal of pricing flexibility in this market. However, as an oral therapy in the US market, there may be additional downward price pressure for this agent. There is also an increasing emphasis on cost-effectiveness studies that will need to be addressed in the development plan.

Dosing: Discovery is currently targeting an oral dosage form. In general, oral therapies are preferred by physicians and patients because of the convenience to the patient. However, this form may not be the best choice for some people who already have certain digestive system symptoms (vomiting, diarrhea, or severe nausea), cannot swallow liquids or pills, or cannot remember when or how many pills to take. Additionally, in the US market there are several unique factors that currently do not favor oral therapies. Novel oral therapies are not currently reimbursed by Medicare, a significant payer for the oncology patient population. Also, 40-60% of a community oncologist's income is generated through the administration of IV drugs. An oral therapy would not be a source of revenue to the physician.

Clinical Studies

Clinical studies across a wide range of solid tumors will be initiated, including but not limited to breast cancer, non small cell lung cancer, ovarian cancer, pancreatic cancer, etc...

Final indications pursued will depend from the results of the phase II studies.

MMPI (ABT-518) 2001 Plan Development Cost Summary

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P's Exhibit EK

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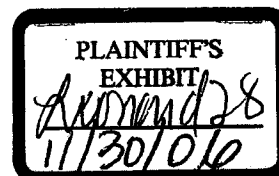
ABT-594

Descriptive Memorandum

February 2001

Abbott Laboratories

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ABBT246076

ABT-594 Opportunity Overview

ABT-594 is a non-opioid, non-NSAID analgesic that is a potent and selective neuronal nicotinic receptor (NNR) agonist being studied for the treatment of pain. ABT-594 is 30 to 100-fold more potent and equally efficacious to morphine in several well-characterized animal models of pain. The preclinical side effect and dependency liability profile of ABT-594 is superior to that of morphine.

ABT-594 is orally administered, and BID dosing is expected. Its initial targeted indication is symptomatic treatment of diabetic neuropathic pain. It is covered by a composition of matter patent through June of 2016, and also has a use patent pending in analgesia that would provide protection through September of 2017.

The IND filing of ABT-594 was in December 1998. A Phase IIb (dose ranging) trial began April 2000 in diabetic neuropathic pain. A Go/No Go decision for clinical efficacy is expected June 2001. The NDA filing is expected in 3Q2003. Development of additional formulations is under consideration (parenteral, transdermal, extended-release).

U.S. sales in 1999 for the key neuropathic pain treatments, Neurontin, carbamazepine, and tricyclic antidepressants (TCAs), are estimated to be \$350 million. Neurontin sales account for the bulk of this, with an estimated 40% of this antiepileptic drug's sales being for neuropathic pain. Neurontin's 2000 sales are expected to reach \$1 billion with perhaps 50% of its use in neuropathic pain. This dollar market value likely underestimates this market's potential due to a number of factors. Only the anticonvulsant, Tegretol (carbamazepine), currently off patent, and Lidoderm, a lidocaine patch, have specific indications for a type of neuropathic pain (trigeminal neuralgia and post-herpetic neuralgia, respectively) in the U.S. Currently, there is an unmet market need for novel neuropathic pain treatments such as ABT-594. Therefore, this compound is likely to be well received in this arena. Outside the U.S., Neurontin recently received an indication in the U.K. for the treatment of neuropathic pain. Despite these opportunities, there has been little to no funding from the pharmaceutical industry to improve diagnosis and treatment of neuropathic pain and drive market growth.

Ex-U.S. sales of carbamazepine and Neurontin for treatment of neuropathic pain are estimated to be approximately \$140MM in 1999. Carbamazepine is still the treatment of choice ex-U.S., with estimated sales of approximately \$90MM in neuropathic pain. Neurontin has achieved only \$53MM in sales for this pain segment, with a price approximately 3-4 times that of carbamazepine, suggesting a patient share of only 10-20%.

Nociceptive pain is categorized by duration (acute or chronic) and by severity (mild, moderate, and severe). The mild and, to a lesser extent, moderate segments have multiple product entries and are generally well satisfied by OTC products such as aspirin, acetaminophen and ibuprofen. The prescription market for nociceptive pain is made up of four key classes of analgesics: NSAIDs, COX-2s, Opioids (and combination products), and Other Non-Opioids. In 1999, sales for these four classes of analgesics exceeded \$12BB (\$6.7BB U.S., \$5.6BB Ex-U.S.)

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ABBT246077

Market Size / Prevalence

Pain is the most common symptom of disease and the most frequent complaint with which patients present to physicians. Chronic pain, including both neuropathic and nociceptive pain, is considered to be the single most common cause of suffering and disability in the industrialized world with an estimated 25-30% of the population experiencing some form of chronic pain.

Neuropathic pain is a frequent sequela of diabetes, cancer, AIDS and other viral infections, as well as entrapment neuropathies such as carpal tunnel syndrome. Diabetes and its associated complications are increasing at an alarming rate in the United States. Despite advances in treatment, the development of diabetic complications such as neuropathy remains significant. The diagnosed prevalence of diabetic neuropathy is estimated to be about 2 to 3 million patients, with at least 10 to 20% of those patients experiencing painful symptoms (~200,000 to 600,000.) AIDS-related neuropathic pain is estimated to affect approximately 40% of HIV-infected individuals (~14 million.) Post-herpetic neuralgia (PHN) is another virally induced neuropathic pain syndrome. Annually, acute herpes zoster infection (shingles) occurs in almost a quarter of a million people over the age of 60 in the U.S. alone. Pain lasting more than one year has been reported in 22% of patients over the age of 55 and in 48% of those over 70 years of age. In cancer, nerves can be damaged by mechanical distortion from a tumor mass, infiltration by tumor, chemotherapy, or radiation therapy and, therefore, neuropathic pain is common. An estimate of the prevalence rate for cancer-related neuropathic pain in the U.S. is 200,000 people.

Chronic nociceptive pain categories include osteoarthritis (OA), chronic back and neck pain, rheumatoid arthritis (RA), and cancer pain. These diagnoses are expected to become more prevalent as the population ages. Current overall prevalence for these disorders is staggering (over 200 million worldwide) and, although the diagnosed and treated populations are lower, improved treatment options and awareness have the potential to drive significant growth. OA is one of the most common nociceptive pain conditions treated by primary care physicians and three-fourths of OA sufferers surveyed indicate that the disease interferes with their daily activities. Chronic back and neck pain are also highly prevalent and represent an estimated 40% of a primary care physician's (PCP's) chronic pain patient population.

Competition, Current Marketed Products:

The following tables show the factored U.S. and ex-U.S. prescription and sales volume for key neuropathic pain therapies in 1999.

1999 Key Neuropathic Pain Products, Estimated TRxs				
Product/Class	1999 U.S. TRx (MM)	U.S. TRx CAGR '97-'99	1999 ex-U.S. TRx (MM)	ex-U.S. TRx CAGR '97-'99
Neurontin	3.3	26.3%	N/A	N/A
carbamazepine	1.0	12.6%	N/A	N/A
TCAs	8.2	1.1%	N/A	N/A
TOTAL	12.5	5.6%	N/A	N/A
Source: IMS, factored for neuropathic uses.				
N/A = not available				

1999 Key Neuropathic Pain Products, Estimated \$ Sales				
Product/Class	1999 U.S. Sales (\$MM)	U.S. Sales CAGR '97-'99	1999 ex-U.S. Sales (\$MM)	ex-U.S. Sales CAGR '97-'99
Neurontin	\$308	28.7%	\$53	57.6%
carbamazepine	\$17	13.1%	\$87	2.5%
TCAs	\$26	-3.3%	N/A	N/A
TOTAL	\$351	21.7%	\$140	10.1%
Source: IMS, factored for neuropathic uses; Ex-U.S. data includes retail pharmacy data from all audited markets				
N/A = not available				

Competition, Products in Development

Almost 100 compounds are currently in development for prescription pain management, though some of these compounds are also being developed for non-analgesic indications. Most of the analgesic compounds in the pipeline represent incremental improvements over the opioids or NSAIDs, or consist of new formulations or delivery mechanisms for the standard analgesics. Fewer than 30% of the compounds in development have novel mechanisms of action. Drugs with novel mechanisms are expected to provide the bulk of promoted competition for ABT-594.

In addition to the novel analgesics in the table below, a number of new formulation and combination products, most often containing an opioid, are in development. Second generation COX-2s are also in development but are not likely to represent major breakthroughs on the scale of the first generation products.

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ABBT246079

Analgesia Development Pipeline – Key Novel Agents				
Product	Company	Mechanism	Phase	Comments
pregabalin	Pfizer	Unknown; possibly through (2 nd) subunit binding	III	Neuropathic pain; chronic pain, follow-up to Neurontin
saredutant	Sanofi	NK-2 receptor antagonist	II	General pain; MOA losing favor; active program
ZD4952, ZD 6416	Zeneca	Prostaglandin receptor antagonist	II	Moderate to severe pain, neurogenic pain
GV196771	Glaxo	Glycine antagonist	II	Chronic pain; showing promise
Tepoxalin	Johnson & Johnson	COX/5-LO inhibitor	II	OA, described as 'steroid replacing anti-inflammatory drug'
darbufelone	Parke-Davis	COX/5-LO inhibitor	II	General pain
117mSn DTPA	Brookhaven National Lab/Diatide	Unknown	II	Cancer pain Bone cancer (preclinical)
cizolirtine	Esteve	Substance P agonist	II	Analgesia, antipyretic
ADD 234037/ harkoseride	Houston University	Glycine NMDA associated antagonist	II	Neurogenic pain
LY303870/ lanepitant	Eli Lilly	Neurokinin 1 antagonist	II	Pain (migraine – discontinued)
colykade devacade	Merck	Cholecystokinin B antagonists	II	Pain (UK)
RPR 100893 dapitant	Aventis	Neurokinin 1 antagonist	II	Pain (France)
prosaptide TX14A	Myelos Neurosciences	Unknown	I/II	Diabetic neuropathies, Pain
CNS 5161	Cambridge NeuroScience	Glutamate antagonist, NMDA receptor antagonist	I	Neurogenic pain
HCT-3012	NicOx	Nitric oxide NSAID	I	Pain and inflammation
Sources: ADIS, IMS, Decision Resources, company reports				

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ABBT246080

Analgesia Development Pipeline – Nicotinic Mechanisms			
Product	Company	Phase	Comments
GTS-21	Taisho	II	Target is Alzheimer's disease; may have preclinical pain program; looking for partner
CMI 980	Cytomed	Preclinical	Target is pain; epibatidine analog
SIB-T1887	Sibla	Preclinical	Target is pain
FID 072021	Fidia	Preclinical	Target is pain; not actively funding
Sources: ADIS, IMS, company reports			

Unmet Needs

In general, a significant unmet need exists for safer, non-abusable, non-addicting, non-tolerance-producing, and non-scheduled efficacious oral and parenteral analgesic products for the treatment of moderate to severe neuropathic and chronic nociceptive pain.

Unmet Market Needs and the Impact of the Pipeline	
Unmet Need	Pipeline Impact
Efficacy in moderate to severe pain without tolerance, dependence or abuse potential	Novel nicotinic agents like ABT-594 may provide efficacy in more severe pain states without opioid-like liabilities.
Efficacy in neuropathic pain	Pregabalin may provide incremental improvement in neuropathic pain efficacy over gabapentin, but may also have increased frequency of adverse events. Novel nicotinic agents like ABT-594 appear to have efficacy in neuropathic pain, based on animal models.
Reduction in the GI bleeding risk of NSAIDs	COX-2 inhibitors appear to reduce the incidence and severity of GI ulcers and bleeding; second generation COX-2s may increase therapeutic window further; ABT-594 may need to demonstrate low G.I. complication rate.
Overcome ceiling effect of NSAIDs	Preclinical studies did not indicate a ceiling effect for novel nicotinic agents like ABT-594.
Extended dosage intervals or novel delivery mechanisms for improved compliance and convenience	Once weekly dosing formulations being explored for COX-2s, etc. Transdermal patch technology improvements likely; may need to provide line-extension / alternate formulations for ABT-594.
Therapies aimed at disease modification, prevention	Agents that decrease rate of diabetic complications (e.g., aldose reductase inhibitors) or directly treat neuropathy (bimoclonol) may decrease incidence of neuropathic pain; thereby decreasing available market for ABT-594.

[FILENAME]

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ABBT246081

Product / Development Background**Scientific Rationale for ABT-594**

Recent findings in the understanding of pain mechanisms have led to new conceptual approaches to clinical pain and a new understanding of potential novel molecular targets for analgesic drug development. Molecular targets have included modulators of glutamate neurotransmission (NMDA antagonists), ion channel modulators (neuron specific calcium channels, TTX-resistant sodium channels), neurokinin antagonists (NK-1), and novel anti-epileptics targeting the calcium receptor. None of these approaches has yet produced compounds exhibiting broad-spectrum analgesic efficacy with decreased side effect liability.

ABT-594 is a non-opioid, non-NSAID analgesic that is 30- to 100-fold more potent and equally efficacious to morphine in treating moderate to severe pain in several well-characterized animal models of pain. The preclinical side effect and dependence liability profile of ABT-594 is superior to that of morphine. Mechanistically, ABT-594 is a potent and selective neuronal nicotinic receptor (NNR) agonist with high oral bioavailability in rat, dog, and monkey.

In pre-clinical studies, ABT-594 rapidly distributes to the brain following systemic administration and, like morphine, can work at multiple levels in the central and peripheral nervous system to modulate pain perception. ABT-594 produces antinociceptive effects by interacting at both central and peripheral nAChRs. Injections of ABT-594 into brain at doses 1000-fold lower than given peripherally produce marked antinociceptive activity, indicating that ABT-594 can also activate descending pathways from the CNS to modulate pain processing. It also inhibits the release of the primary nociceptive transmitters, substance P and calcitonin gene related peptide (CGRP) *in vitro*, at the level of the dorsal horn of the spinal cord suggesting that ABT-594 can attenuate mechanisms leading to neurogenic inflammation, central sensitization and consolidation of pain-mediated neuronal changes.

ABT-594 is expected to be a highly differentiated product. It is expected to be the first neuronal nicotinic receptor agonist to receive an indication for pain. It has a novel mechanism of action and a potentially broad coverage of chronic pain conditions. In addition, it has an opioid-like efficacy without tolerance, dependence or abuse potential, while having equivalent/superior efficacy to other drugs used to treat neuropathic pain.

Clinical Studies

Human clinical trials began in 1997. Phase I trials with an oral solution formulation indicated that 150ug/day would be the maximum tolerated dose. Results from subsequent phase I and phase II trials with soft elastic capsule (SEC) and hard gelatin capsule (HGC) suggest that higher doses would be tolerated. Phase IIa studies with ABT-594 SEC formulation suggest a trend towards analgesic effect at 75ug BID, the maximum dose studied in this protocol. ABT-594 was generally well tolerated in these studies. The most common adverse events for subjects receiving ABT-594 75ug BID were nausea (15%), headache (13%), dizziness (7%), insomnia (6%), and vomiting (5%).

A phase IIb study for neuropathic pain at higher, titrated doses of ABT-594 began in April 2000 and ends in June 2001. A total of 320 patients is anticipated to be included in the study.

[FILENAME]

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ABBT246082

Considerations**Target Profile:**

The current status of ABT-594's profile vs. target profile is summarized in the table below:

Target Profile Attribute	Probability
Not scheduled (DEA)	High
Very few abnormal Liver Function Tests	High
Few Drug interactions	High
BID / TID dosing	High
No reduced efficacy or increased AEs in nicotine users	High
Onset of action 1.5 – 2.0 hours	High
Neuropathic efficacy	Medium
No tolerance, dependence or withdrawal	Medium
Other safety OK	Medium
No cravings in ex-nicotine users	Medium
Low nausea / vomiting	Low

Label Strategy:

BASE: Indicated for the treatment of diabetic neuropathic pain.

UPSIDE:

- 1) Treatment of pain associated with OA
- 2) Treatment of post-herpetic neuralgia
- 3) Treatment of neuropathic pain
- 4) Treatment of chronic pain
- 5) Treatment of cancer pain

Cost of Goods Sold:

The projected average daily dose is expected to be a maximum of approximately 600 mcg base equivalent / day. Based upon this dosage projection and the estimated cost of bulk drug substance of \$40M per Kg base equivalent, the estimated cost for drug substance at launch will be approximately \$0.024 per day.

[FILENAME]

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ABBT246083

Pricing:

US: Pricing new, and particularly novel, products at a reasonable premium will likely continue to be the norm in the years leading up to the launch of ABT-594. Current forecast assumptions put the price of ABT-594 at a level comparable to Celebrex and Neurontin, grown at a modest 2% per year to launch year AWP of approximately \$95 for a 30 day prescription.

Ex-US: New pain medications must demonstrate a true advantage in efficacy and/or side effects to receive regulatory approval, especially by the European Medicines Evaluation Agency (EMA); assuming the target efficacy and tolerability profile of ABT-594 is achieved, ABT-594 would meet this requirement. Because ABT-594 may have application in both neuropathic and chronic nociceptive pain, the ex-U.S. pricing assumption for ABT-594 is comparable to COX-2 pricing. The current average price for COX-2's is approximately \$1.10 per day; however, this reflects a large percentage of sales in "free-pricing" countries, where COX-2s launched first, which tend to have higher than average prices. Therefore, the average ex-U.S. price for ABT-594 is assumed to be \$0.90/day.

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ABBT246084

Leonard Deposition Exhibit 30

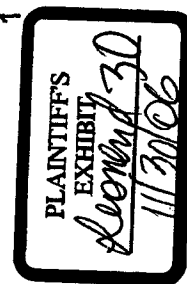
P's Exhibit MJ

Part 1

Portfolio Analysis of 2001 Abbott Global Pharmaceutical Development Assets

April 20, 2001

4/20/01



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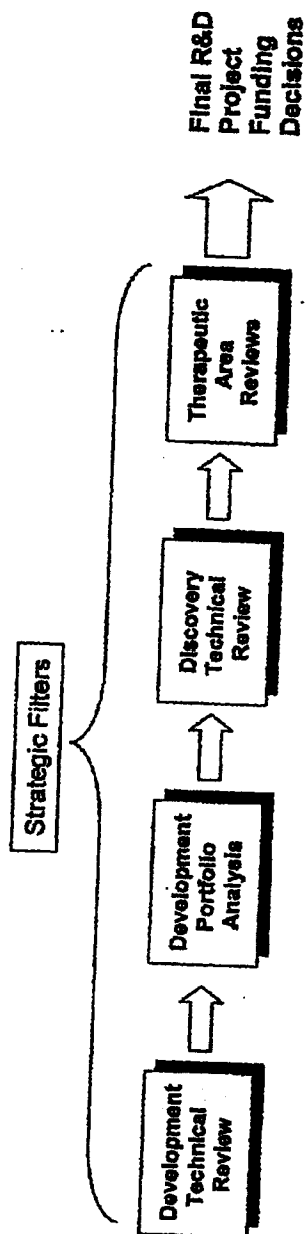
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Contents

- Introduction
- Portfolio Analysis Process and Database Content
- Abbott Global Pharmaceutical Development Asset Pool Characterization
- Analysis of Potential Development Portfolios – Issues and Trade-offs

4/20/01

Today's meeting is only one component of the process to arrive at final 2001 Global Pharmaceutical R&D project funding decisions.



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3

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Objectives of today's meeting

- Understand the total Abbott global pharmaceutical asset base with regard to value creation potential, uncertainty profile, phase mix, etc.
- Understand various trade-offs of different funding scenarios with respect to potential value creation, asset utilization, budget implications, etc.
- Provide strategic perspective for final development budget prioritization decisions in early May.
- It is not an objective to recommend one particular funding scenario or decide which projects to fund or not fund.

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Portfolio Analysis Process and Database Content

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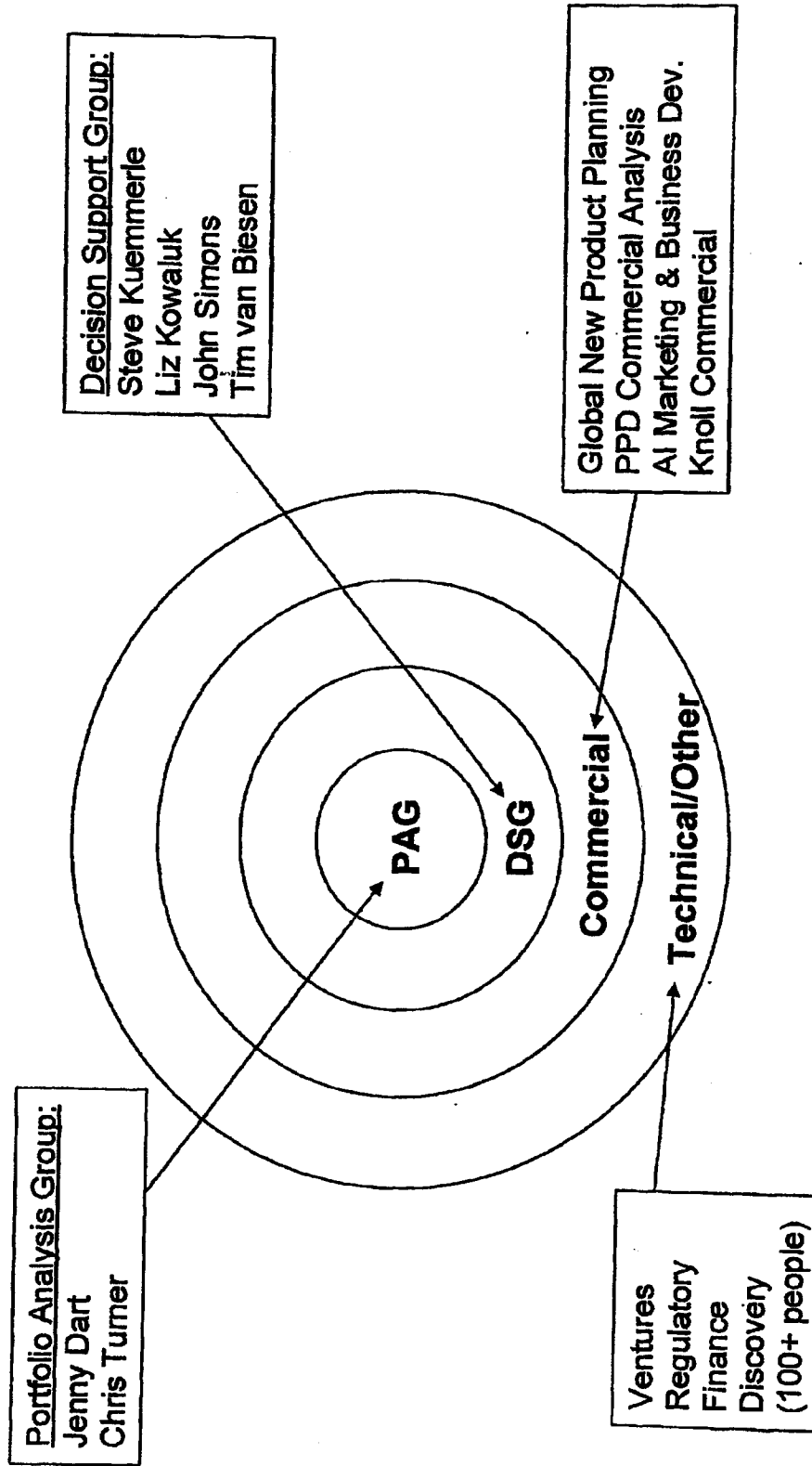
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Assets included in this analysis

- Included:
 - PPD pharmaceutical assets: Post-DDC - Phase IV
 - Knoll development projects:
- Not included:
 - HPD pharmaceutical assets
 - AI-specific pharmaceutical assets (Uprima)
 - Knoll Phase IV projects previously included in Knoll's promotional budget.
 - Discovery pre-DDC assets

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Many organizations contributed to this process.

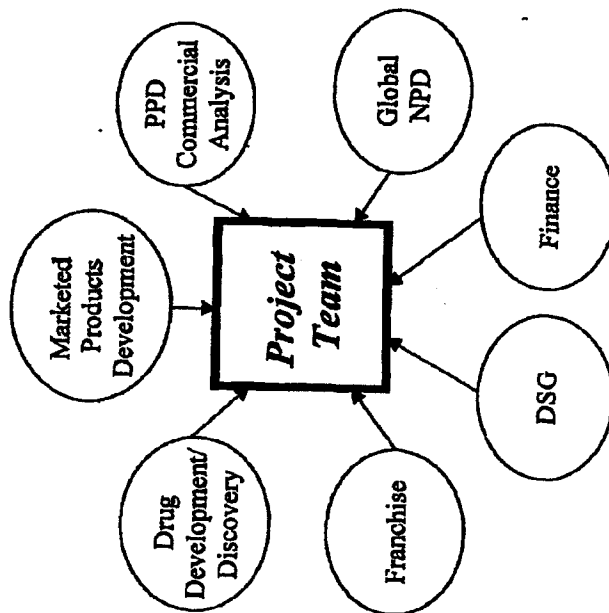


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Overall data generation, review and analysis process

Data Generation & Team Review



Senior Management Review

Probabilities

- Dan Norbeck
- John Leonard
- Dave Pizzutti

Commercial

- New Product Dev't
- Ed Fiorentino
- John Arnott

R&D Costs

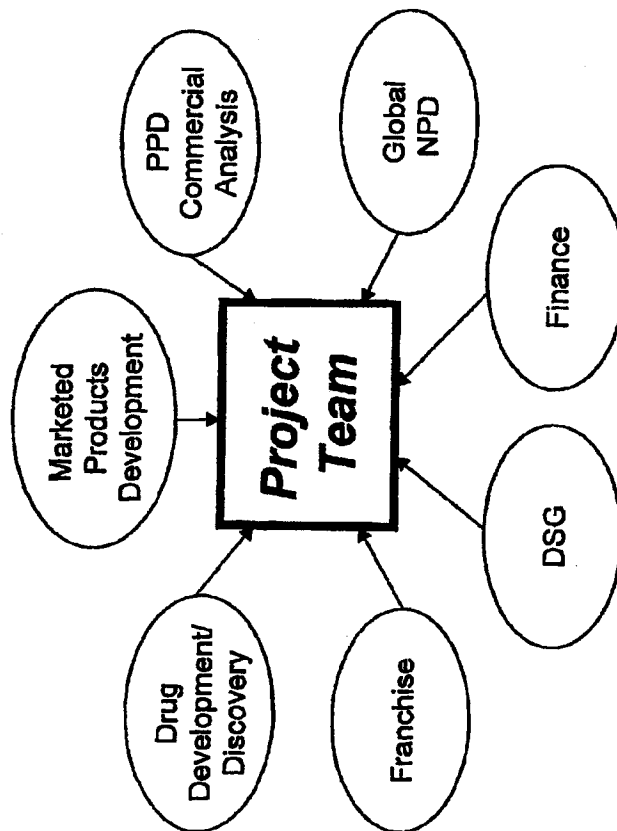
- Bob Funck
- Iris Loew-Friedrich
- Steffen Roellinger
- Key Venture Contacts

Data Analysis & Synthesis

- Portfolio Analysis Group
- Decision Support Group

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The project teams were global and cross-functional.



Abbott Project Teams

- ABT-773
- ABT-492 & ABT-677
- Clari & Omnicef
- HIV
- Tricor
- Gengraf
- Neuroscience
- Depakote
- Oncology
- Urology

Knoll Project Teams

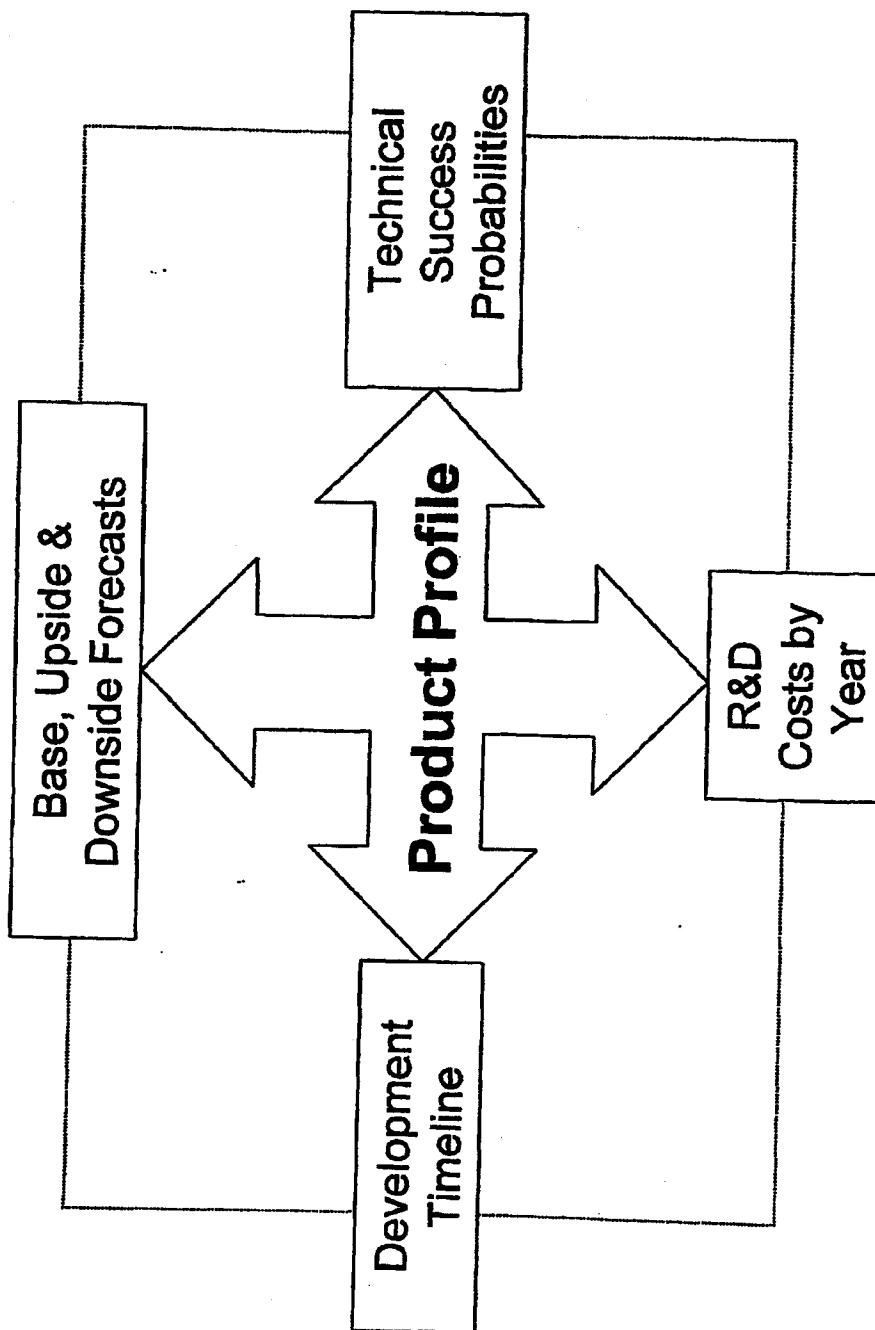
- AU-224
- Clivarine
- D2E7
- Darusentan
- Dilaudid
- Ganaton
- Hokunalin Tape
- J-695
- PEG Hirudin
- Propafenone SR
- SEGARD
- Sibutramine
- T4/T3

The project team is designed to bring together people across multiple functions to ensure that the assumptions underlying the forecasts and technical success probabilities are representative of the collective knowledge of the organization.

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The product profile assumptions are the foundation for all project data contained in the database.



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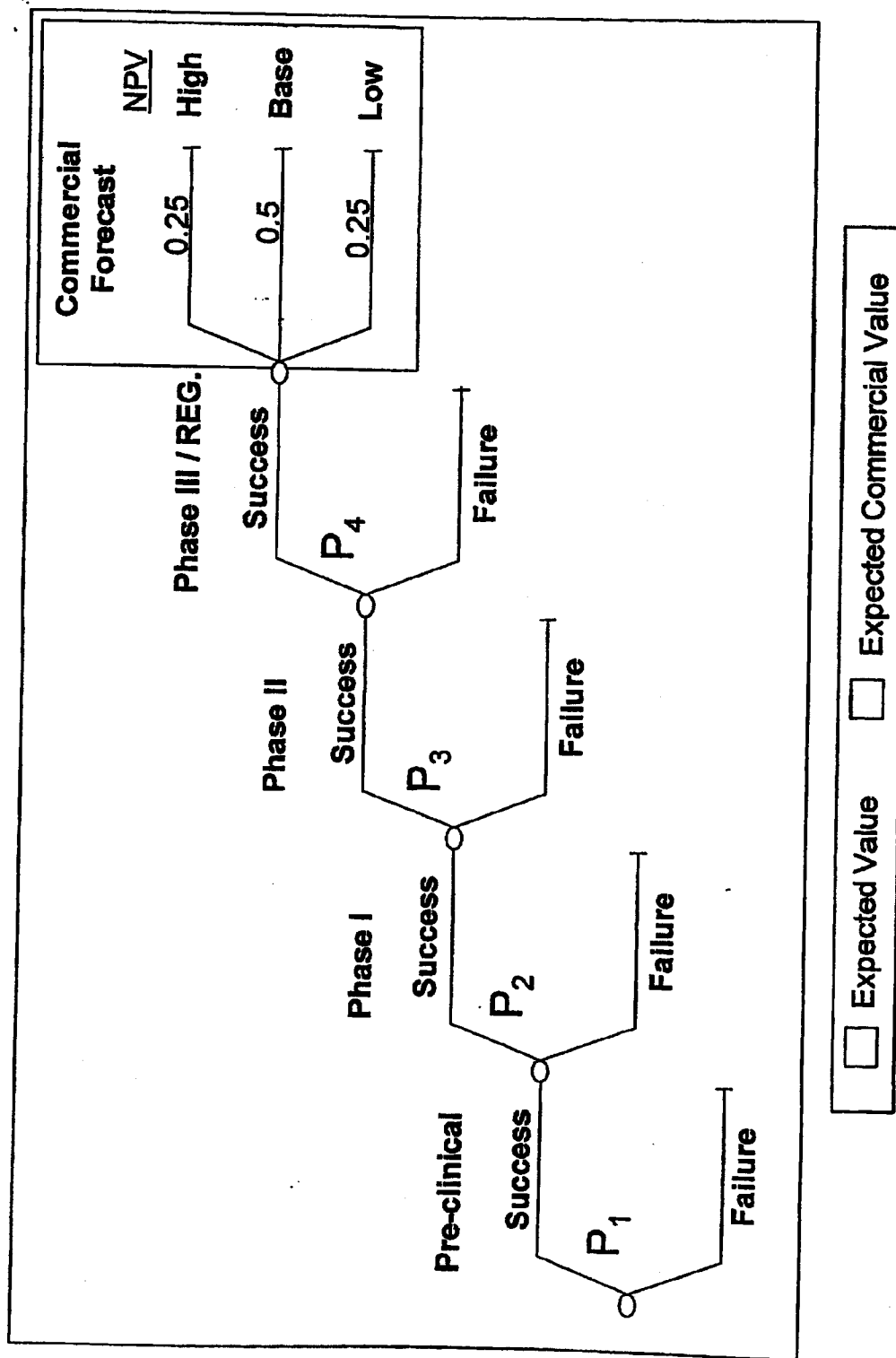
We use decision analysis methods to value R&D assets.

- Allows for the incorporation of uncertainty in asset valuation.
- Provides a common language for comparing relative value between R&D assets.
- Provides a quantitative method for evaluating the relative values and trade-offs between various portfolio options.

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The calculation of expected value in the portfolio analysis model incorporates both technical and commercial uncertainty.



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Key definitions - project value measures

- Expected Value (EV):
 - Risk adjusted Net Present Value (NPV) of a project
 - Incorporates base, upside and downside division margin projections.
 - Incorporates technical risk by phase.
 - NPV Division Margin calculated on years 2001-2015.
 - Discount rate = 12.5%
- Expected Commercial Value (ECV):
 - Probability-weighted average of base, upside and downside division margins.
- Productivity Index (PI):
 - Ratio of Expected Value to Expected R&D cost
 - "Bang for the Buck"

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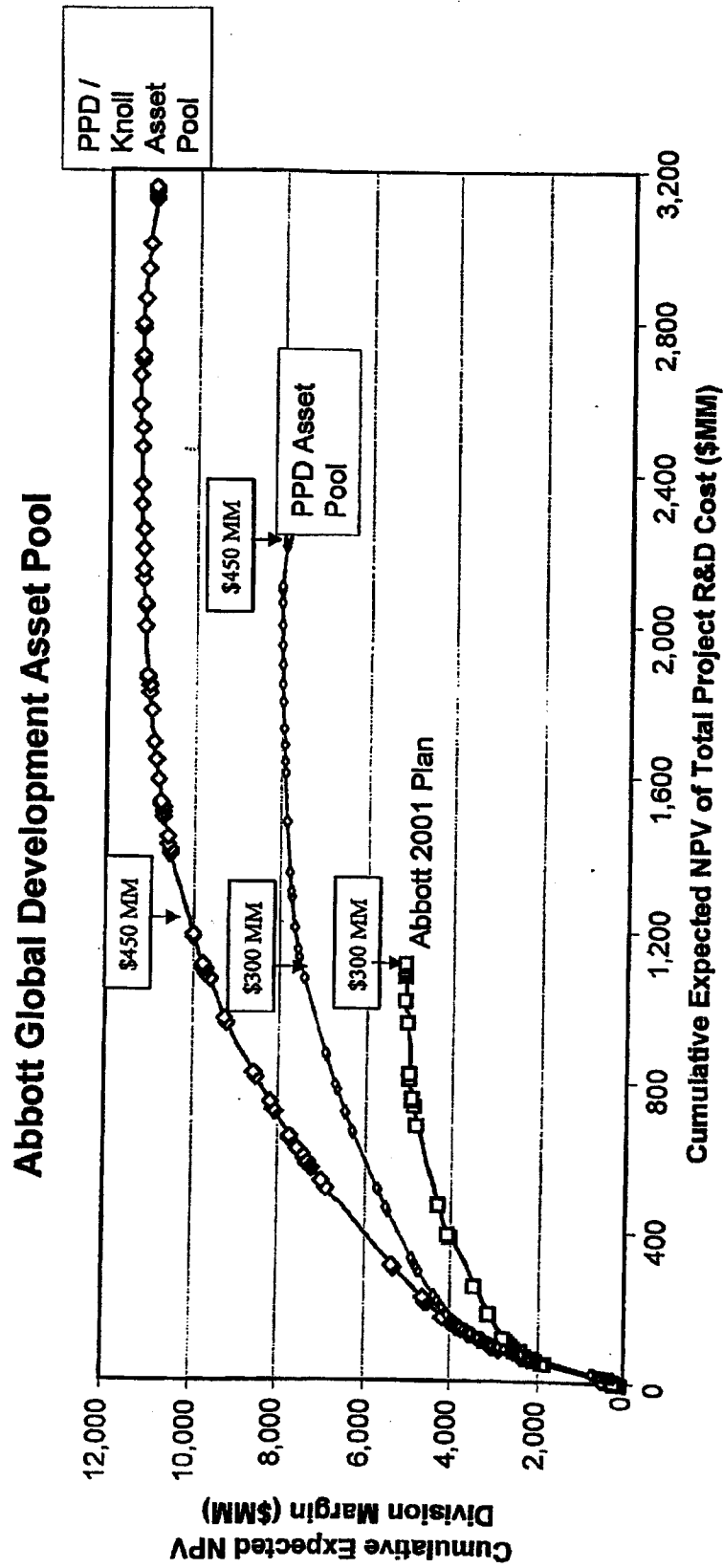
***Abbott Global Pharmaceutical
Development Asset Pool
Characterization***

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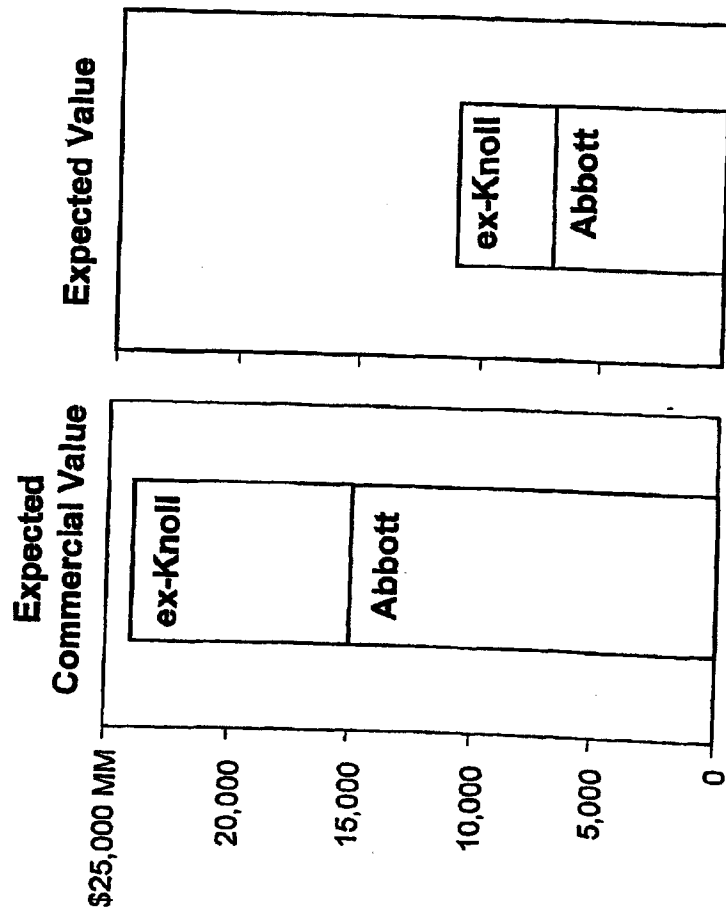
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The Knoll acquisition has significantly improved the potential productivity of Abbott R&D investments.



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The development asset pool has an expected value of \$11B, and an expected commercial value as high as \$24B if all projects are successful.



- Knoll-originated programs contribute 36% of the value, on both an expected value and potential expected commercial value basis.
- The overall risk profiles of Abbott- and Knoll-originated asset bases are similar.
- 2001 R&D funding requests: \$720MM
 - Abbott-originated: \$450MM (63%)
 - Knoll-originated: \$270MM (37%)

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The value of Abbott and Knoll contributions to the total development asset pool differ by current phase of development.

Expected Commercial Value (if successful)

	Depakote	Sibutr.	Clari	Feno.	Cilv.	Propaf.	Hydr.	Dil.	Omni
Ph. IV	Kaletra								
Ph. III	D2E7	627	SEGARD	773	822				
Ph. II	594	PEG Hir.	J695	Ganaton	Darus.	190555	201640		
Ph. I	963	510	AU224	518	751	492	089	420627	
Pre-Clin.	828	598	T4/T3	Hok. Tape	677				

☐ \$847 MM
☐ \$529 MM
☐ \$411 MM
☐ \$315 MM

Abbot Knoll
☐ ☐

Area of bubble = expected commercial value.

Circle size proportional to Expected Commercial Value (\$MM) of an asset with \$450 MM peak year sales in each respective development phase

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Factoring in technical and regulatory success probabilities does not significantly change the relative value contributions.

Expected Value

	Depakote	Sibutr.	Clari	Feno.	Cliv.	Propaf.	Hydr.	Dil.	Omnid
Ph. IV	Kaletra								
Ph. III	D2EZ	627	SEGARD	773	822				
Ph. II	594	PEG Hir.	J695	Ganaton	Darus.	190555	201640		
Ph. I	963	510	AU224	518	751	492	089	420627	
Pre-Clin.	828	598	T4T3	Hok. Tape	677				

Abbot Knoll

\$533

\$147

\$50

\$18

Area of bubble = expected value.

Circle size proportional to Expected Value (\$MM) of an asset with \$450 MM peak year sales in each respective development phase

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Requested 2001 R&D funding by program, phase and origin

	\$720 MM											
Ph. IV	Kaletra	Depakote	Sibutr.	Clari	Feno.	Cilv.	Propaf.	Hydr.	Dil.	Omni		\$234 MM
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Ph. III	D2E7	827	SEGARD	773	822							\$251 MM
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							
Ph. II	594	PEG Hir.	J695	Ganaton	Darus.	190555	201640					\$93 MM
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>					
Ph. I	963	510	AU224	518	751	492	089	420627				\$90 MM
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>				
Pre-Clin.	828	598	T4/T3	Hok Tape	677							\$52 MM
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>							

Abbott Knoll
☐ ☐

☐ \$46

☐ \$25

☐ \$15

☐ \$6

Area of bubble = 2001 R&D cost.

☐ Circle size proportional to 2001 R&D cost (\$MM) of an asset with \$450 MM peak year sales in each respective development phase.

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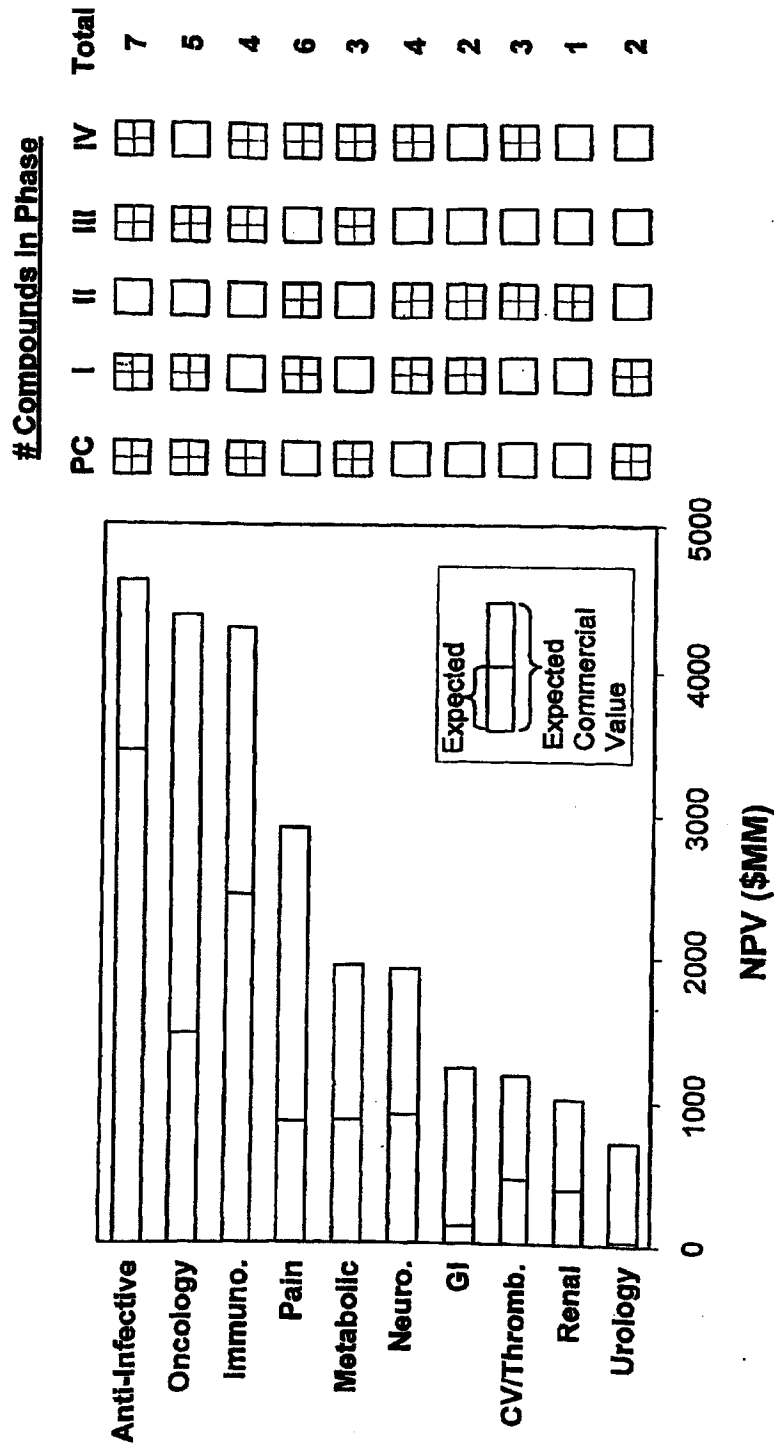
Therapeutic areas represented in the development asset pool

- Anti-infectives (anti-bacterials and anti-virals)
- Cardiovascular/Thrombosis
- Gastrointestinal
- Immunoscience
- Metabolic diseases (diabetes, obesity, thyroid)
- Neuroscience
- Oncology
- Pain
- Renal
- Urology

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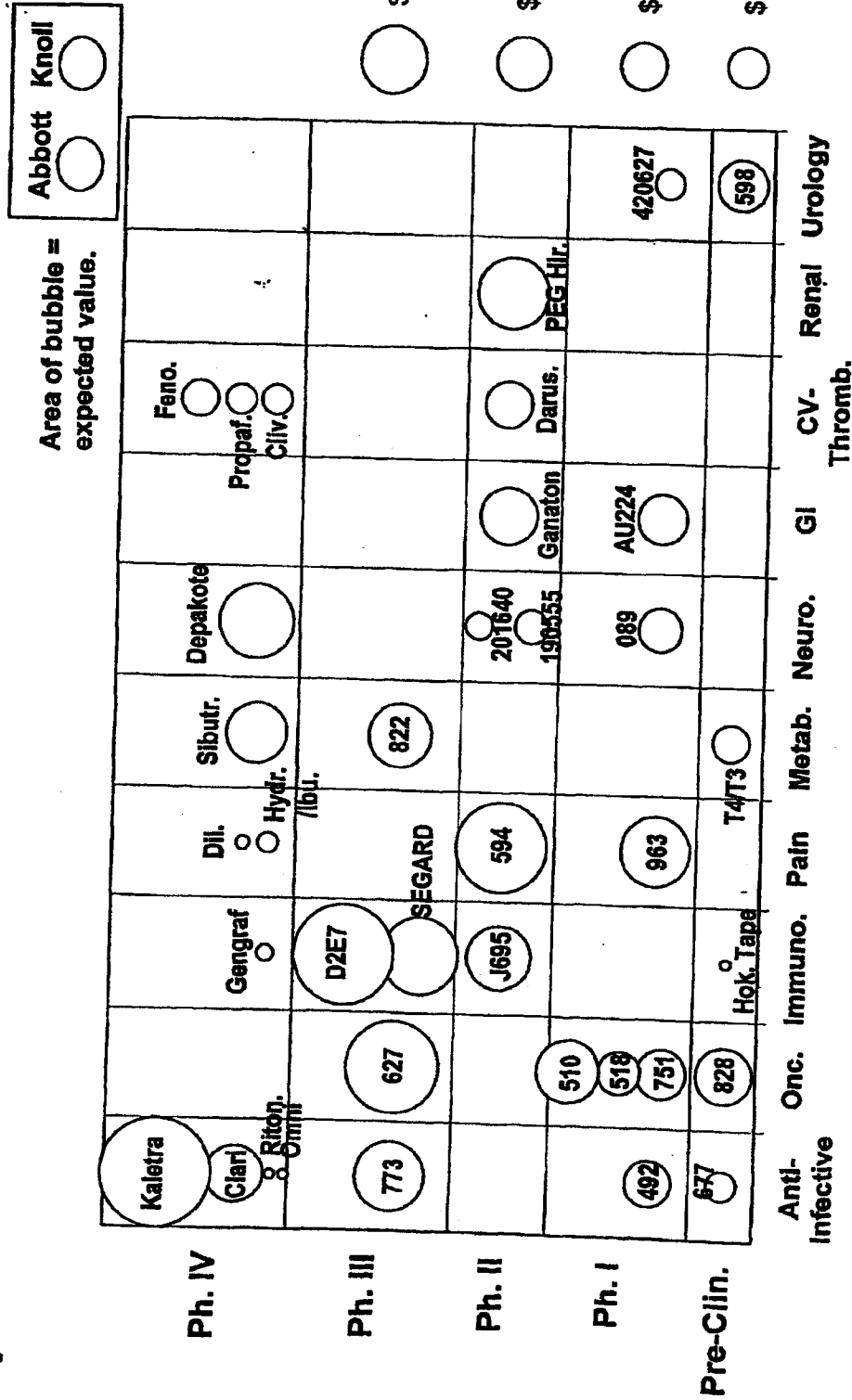
Expected value and expected commercial value for each therapeutic area



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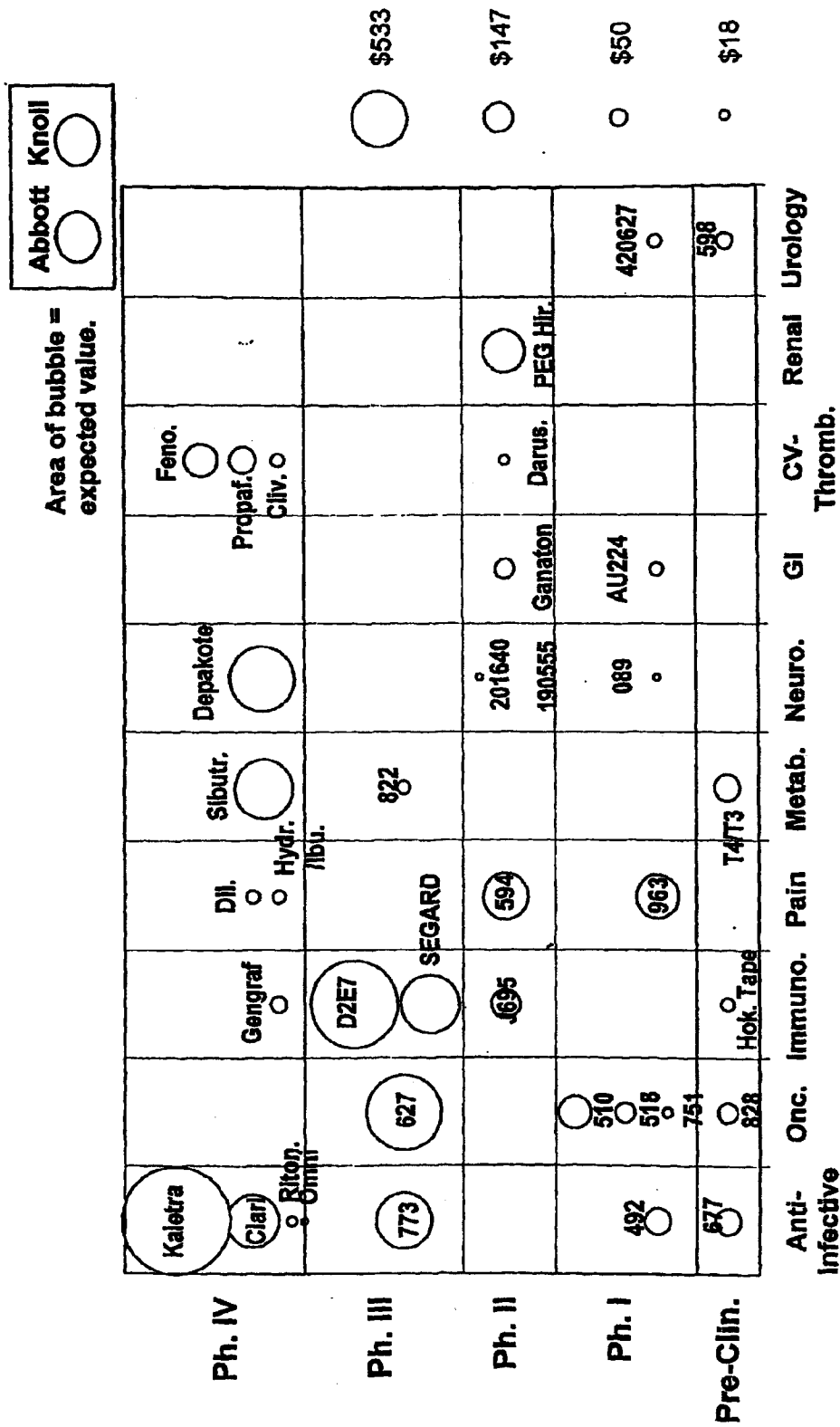
21

Expected commercial value by therapeutic area and phase



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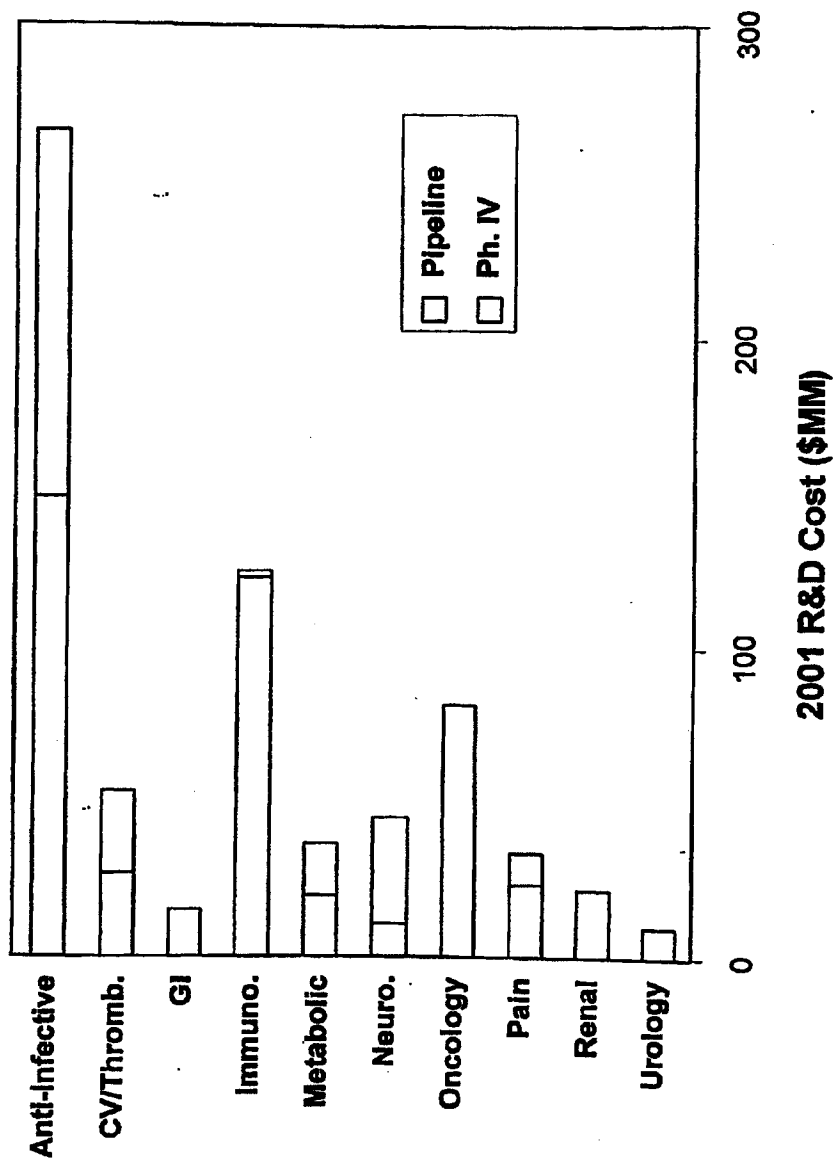
Expected value by therapeutic area and phase



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The 2001 R&D funding requests by therapeutic area



Analysis of Potential Development Portfolios – Issues and Trade-offs

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There are various ways to prioritize projects within the portfolio.

- **Expected Value:** Fund projects according to rank order of expected value.
- **Productivity Index:** Fund projects by rank order of productivity index.
- **Phase Balanced Productivity:** Within each phase, fund most productive projects with objective of achieving product launch consistency.

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Phase Balanced Productivity prioritization balances short-term and long-term assets.

- **Expected Value**
 - Favors late stage development compounds.
 - Selects big development projects over smaller projects.
 - Doesn't ensure most productive use of R&D resources.
 - Not recommended to be used for portfolio prioritization.
- **Productivity Index**
 - Ensures most productive use of R&D resources.
 - Strong bias towards Phase III & IV programs.
 - Late stage bias can result in phase mix imbalance.
 - Used only as productivity benchmark and not as primary portfolio optimization method.
- **Phase Balanced Productivity**
 - Ensures phase mix balance with high productivity.
 - Recommended methodology for portfolio selection, if feasible.

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Phase Balanced Productivity Prioritization

Objective: Fund projects to achieve optimal phase mix to ensure product launch consistency over time, while maximizing overall R&D investment productivity.

“Optimal” Phase Mix: Optimal development phase mix based upon the following factors:

- Technical success probabilities
- 7 year development timeline
- Abbott historical development costs

Optimal Phase Mix			
Phase	Funding %	#NCE's ¹	
PC	9%	8	
I	14%	4	
II	40%	5	
III	37%	4	

* Based on a \$ 400MM budget (\$500MM - \$100MM Ph IV)

Funding Rules: Within each phase, fund most productive projects with objective of achieving “optimal” phase mix:

- Ph IV allocation determined and funded separately based on highest PI ranking.
- Determine relative spending by phase to achieve “optimal” phase mix.
- Allocate funds by phase based upon highest PI ranking.
- “Approved” DDC's funded before future DDC's.

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Candidate portfolios were evaluated on the basis of multiple value measures.

- **Asset utilization**
 - Fraction of available NCEs funded by phase
- **Expected value realized**
- **Phase mix**
 - Allocation of development budget by phase
 - Number of projects per phase
- **Product launch pattern**
- **Productivity index**
- **Therapeutic area mix**
 - Allocation of development budget by therapeutic area
 - Number of projects by therapeutic area
- **Expected sales**
 - Short (2004), Medium (2008), and Long (2012) Term
- **Future R&D cost implications**

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Potential portfolios were analyzed across various total 2001 funding levels and Phase IV allocation scenarios.

- The implications of funding decisions were assessed by analyzing the impact of two key variables:
 - Size of the 2001 Development budget:
 - Range from \$500MM to \$650MM
 - Phase IV allocation:
 - Range from 15-30% of the Development budget
- These issues were not explicitly considered in this analysis:
 - Contractual obligations (e.g. Hancock)
 - Current funding status of projects (2001 plan)

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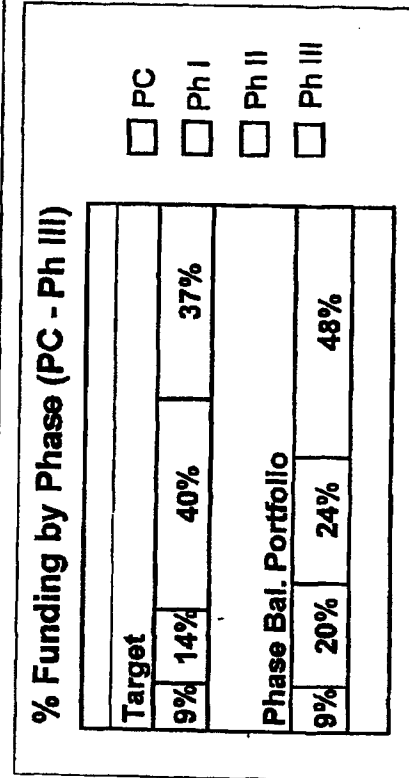
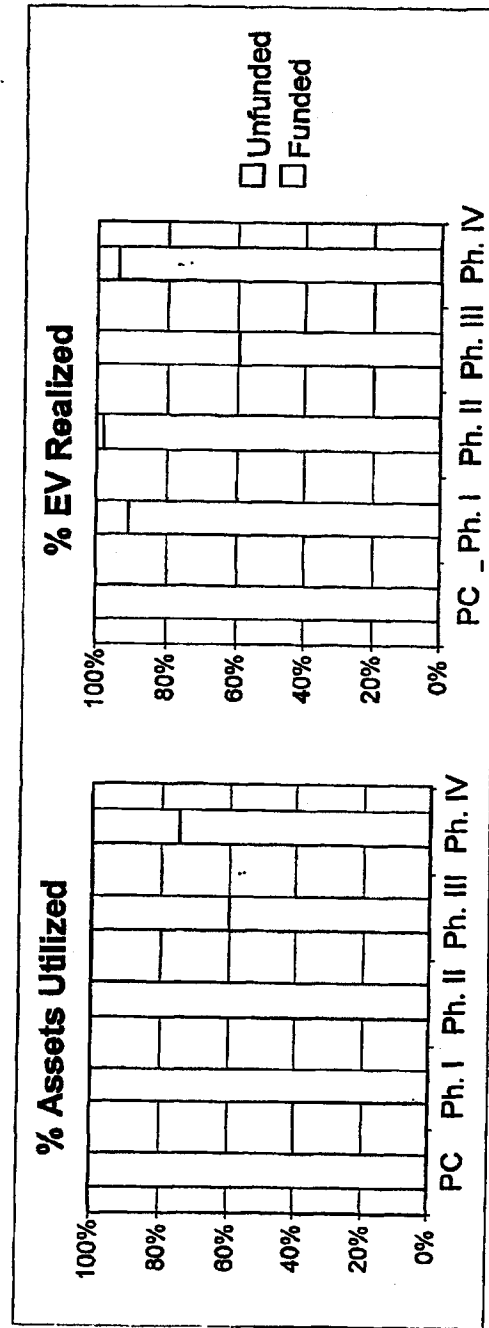
Scenario 1

- Funding Level: \$500MM
- Ph. IV Allocation: 20%
- Phase Balanced Productivity Selection

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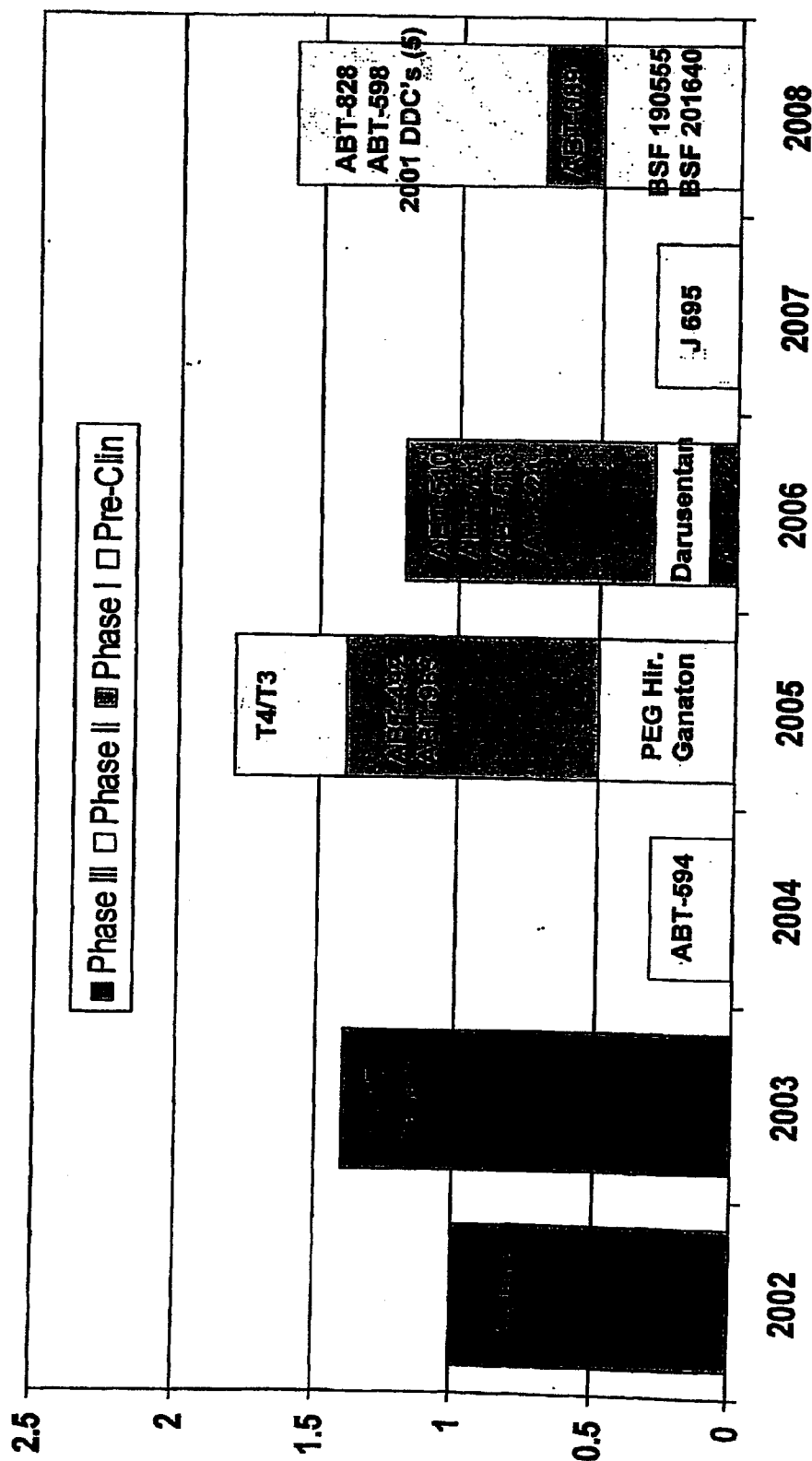
The \$500MM phase balanced portfolio selection results in good utilization of early-phase assets, but limits the ability to fund less productive Ph. III assets.



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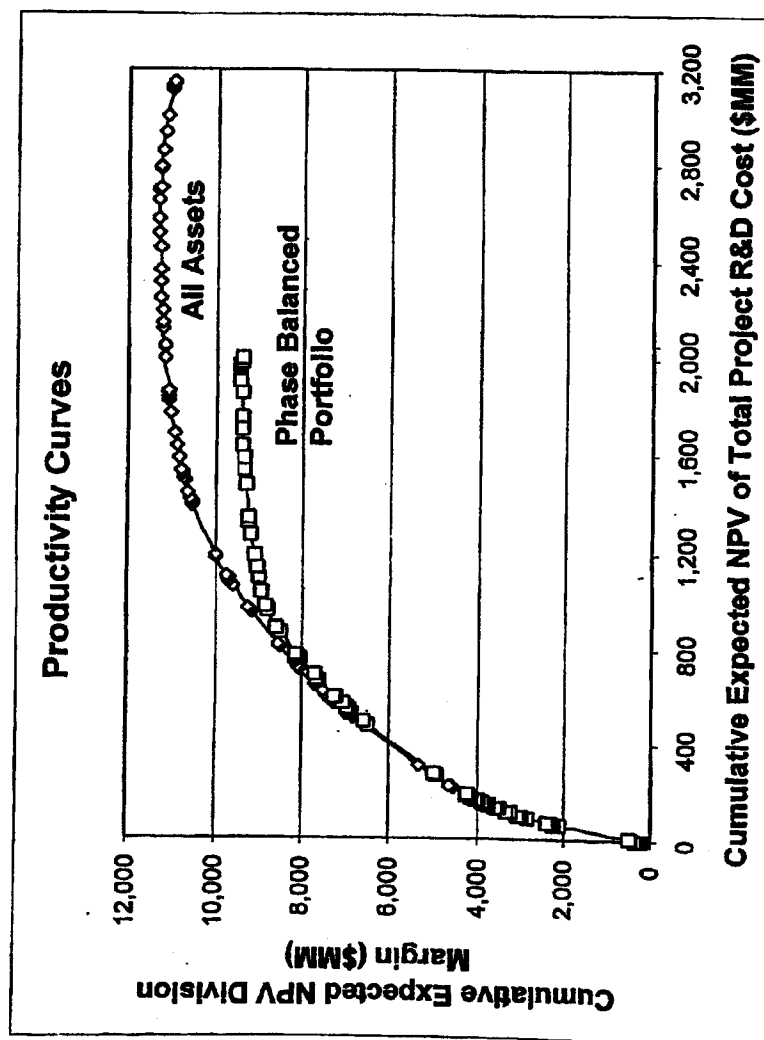
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The \$500MM phase balanced portfolio results in an average of about one expected launch per year over the next 8 years.



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The \$500MM phase balanced portfolio generates an incremental \$4.9B expected value compared to the 2001 Plan (\$300MM), and improves R&D investment productivity.



Phase Balanced Portfolio:

EV: \$9.4B

PI: 4.7

2001 Plan (\$300 MM):

EV: \$4.5B

PI: 4.0

All Assets:

EV: \$11.3B

PI: 4.3

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The main trade-off with this scenario is that two key Phase III assets are not funded.

- ABT-627 and ABT-773 do not meet the funding threshold:
 - The phase-balancing model limits the Phase III-specific budget.
 - Among Phase III programs, ABT-627 and ABT-773 have the lowest productivity indices:

Program	PI	2001 Cost
SEGARD	12.5	\$11.9MM
ABT-822	8.5	\$10.3MM
D2E7	7.5	\$99.3MM
ABT-627	4.3	\$41.8MM
ABT-773	2.5	\$88.0MM

The phase-balance model allocates \$122MM to Ph III projects (\$500MM budget with 20% Ph IV allocation).

Reducing the Ph IV allocation to 15% allows funding of ABT-627 (Ph III budget increased to \$156MM).

- Aside from the obvious commercial implications, there are estimated to be \$75MM in shut down costs for ABT-627 and ABT-773.
- Funding of all Ph III programs in a phase-balanced portfolio requires an increase in the total development budget to at least \$600MM.

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Key trade-offs with \$500MM phase balanced portfolio

Pros

- Excellent utilization of pre-Ph. III assets.
- More than doubles expected value over 2001 Plan with only a 67% increase in spend.
- Average of one product launch per year over next 8 years.

Cons

- Funding is not available for two key Phase III compounds (ABT-627 and ABT-773).
- Significant shut-down costs associated with ABT-627 and ABT-773.
- At least \$600MM would be required to fund ABT-627 and ABT-773 and maintain phase balance.

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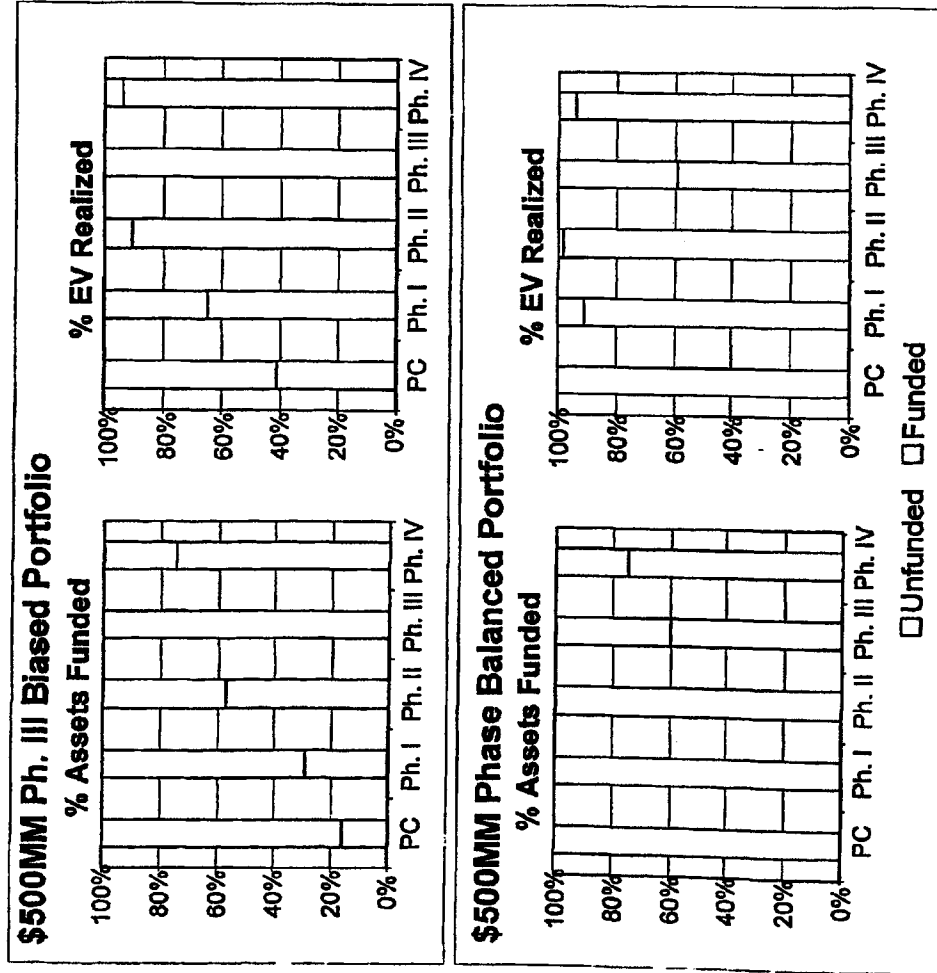
Scenario 2

- ***Funding Level: \$500MM***
- ***Ph. IV Allocation: 20%***
- ***Ph. III Biased Selection (requires all
Ph. III projects to be funded)***

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This Ph. III biased scenario significantly under-utilizes pre-Ph. III assets due to the \$500MM spending limitation.



% Funding by Phase (PC – Ph. III)			
Target			
9%	14%	40%	37%
\$500MM Ph. III Biased Portfolio			
5%	15%	77%	
2%			
\$500MM Phase Bal. Portfolio			
9%	20%	24%	48%

☐ PC ☐ Ph. I ☐ Ph. II ☐ Ph. III

☐ PC ☐ Ph. I ☐ Ph. II ☐ Ph. III

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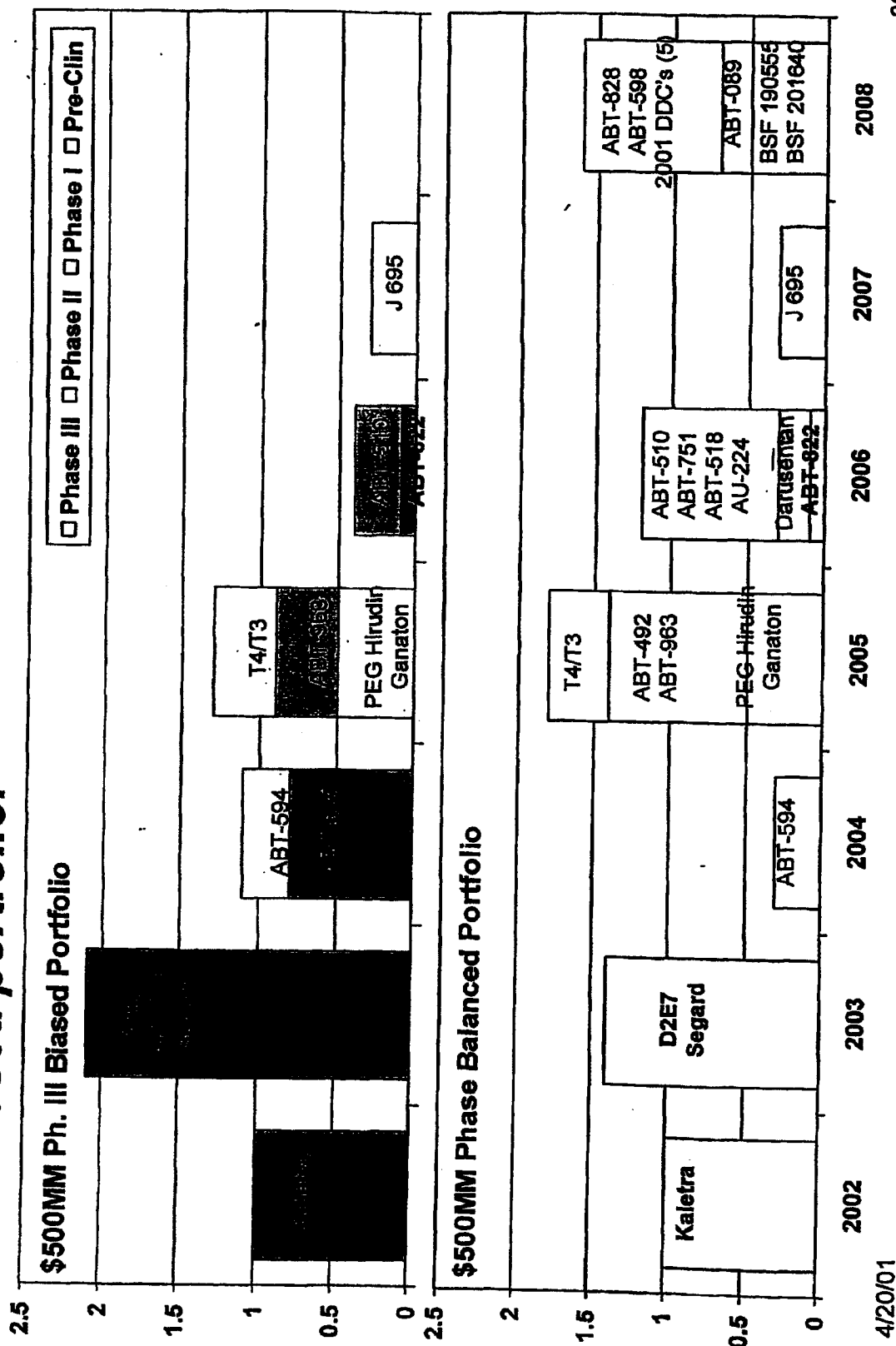
38

Leonard Deposition Exhibit 30

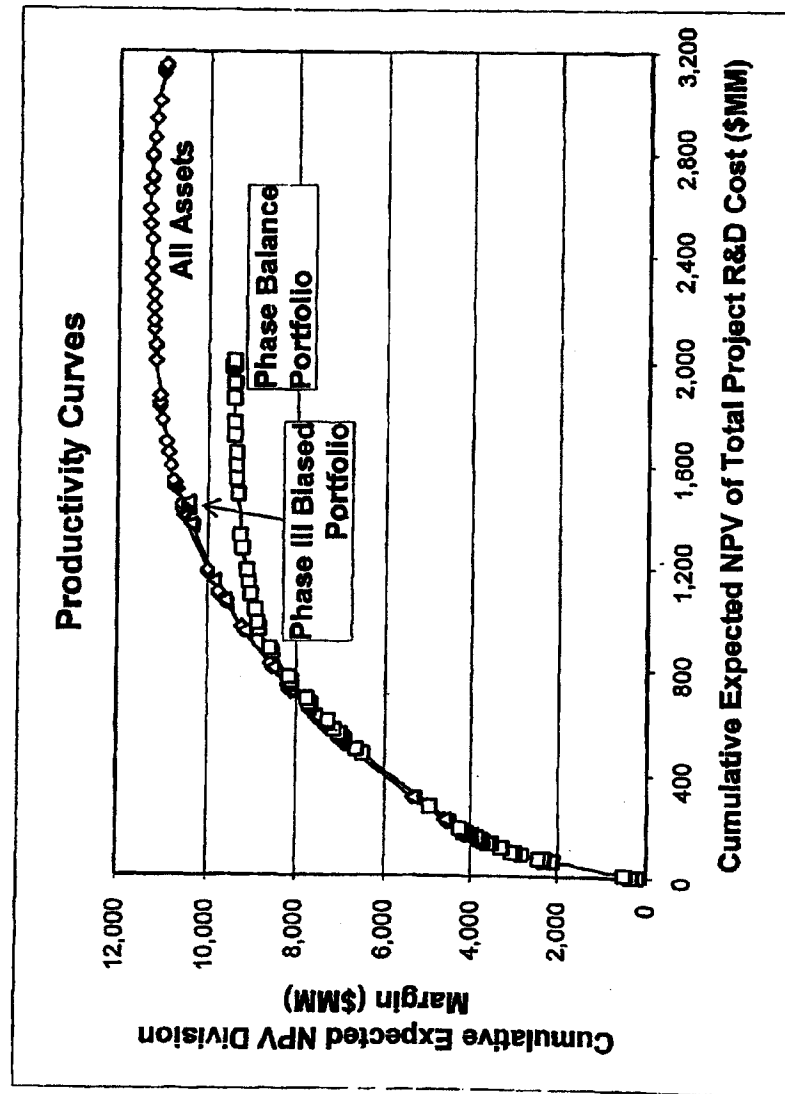
P's Exhibit MJ

Part 2

Expected launches decline after 2005 for the \$500MM Ph. III biased portfolio.



The \$500MM Ph. III biased portfolio generates even more expected value and R&D investment productivity than the \$500MM phase-balanced portfolio.



Ph. III Biased Portfolio:

EV: \$10.4B

PI: 7.2

Phase Balanced Portfolio:

EV: \$9.4B

PI: 4.7

2001 Plan (\$300 MM):

EV: \$4.5B

PI: 4.0

All Assets:

EV: \$11.3B

PI: 4.3

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\$500MM Phase III Biased / Phase IV = 20% Program Detail

Pre-clinical	Ph. I	Ph. II	Ph. III	Ph. IV
T4/T3	ABT-963 ABT-510	ABT-594 Ganaton PEG Hirudin J695	SEGARD ABT-822 D2E7 ABT-627 ABT-773	Clari Kaletra Ritonovir Clivarine: Hemo Fenofibrate Propafenone SR Gengraf Sibutramine Depakote Other Knoll Ph IV
ABT-598 ABT-828 5 Future DDC's Hokunalin Tape ABT-677	ABT-751 AU-224: CRC ABT-492 ABT-089 ABT-518 BSF 420627	BSF 190555 BSF 201640 Darusentan		Dilaudid IR & CR Hydrocodone Omnicef

Funded

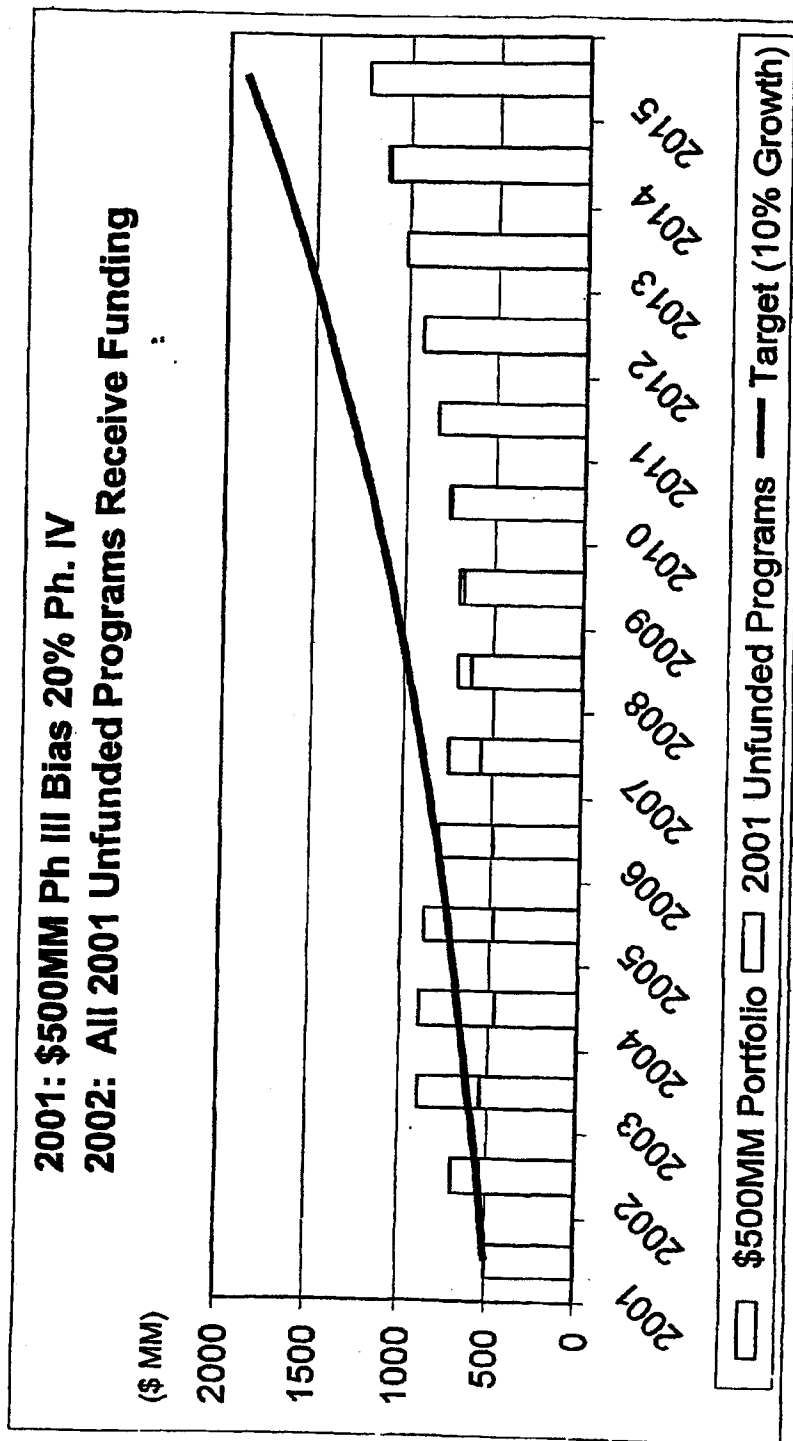
Unfunded

Green: increase to \$500MM Phase Balanced; Red: reduction from \$500MM Phase Balanced

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41

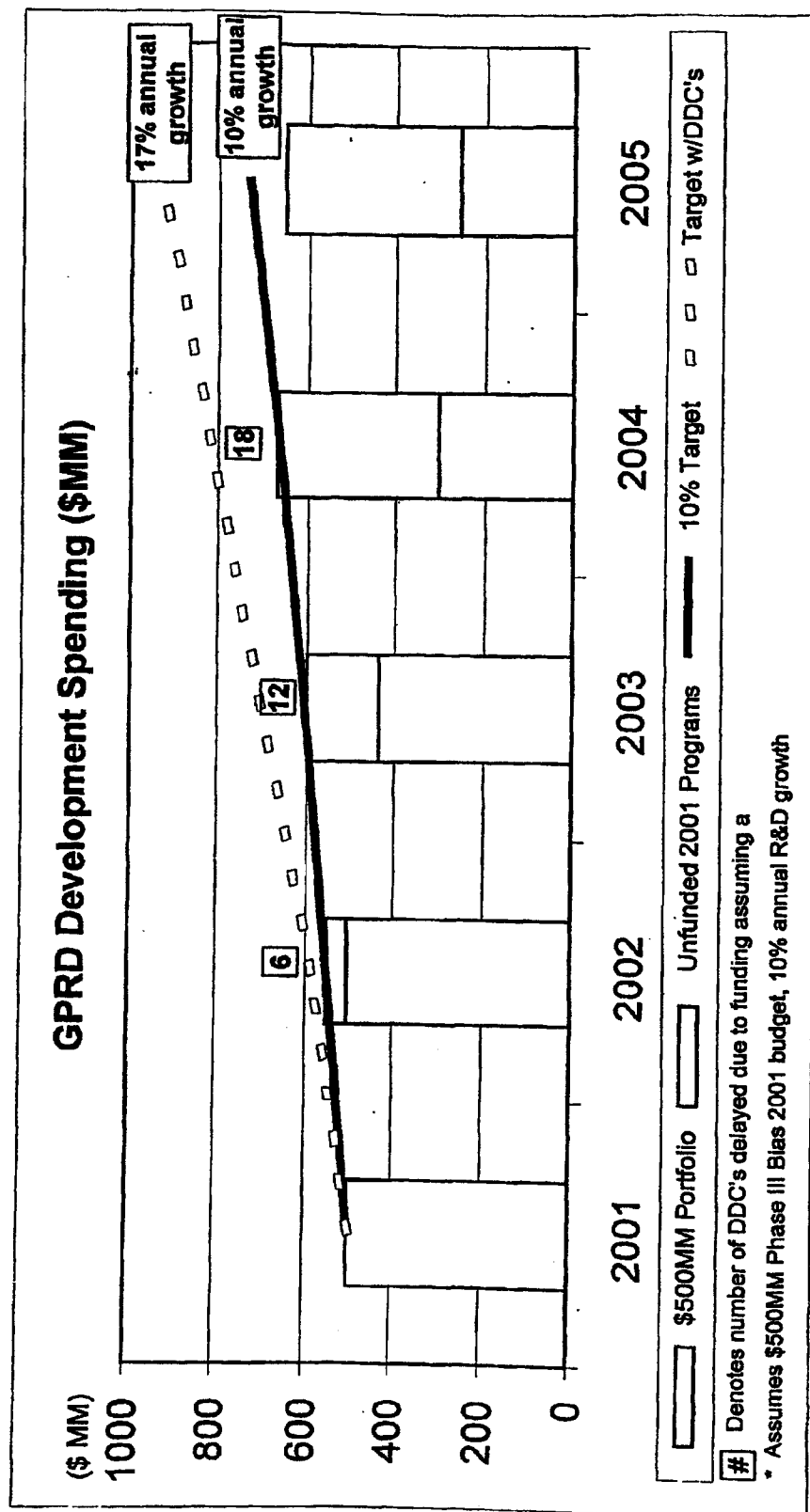
One option to address the under-utilized pre-Ph. III assets would be to delay funding to 2002. This has significant cost implications for 2003 – 2005.



Assumes 6 DDC's per year starting 2002 and growing at 10% annually
 Phase IV budget grows at 10% annually

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With a 10% annual development budget growth rate, it would take until 2004 to put all under-utilized 2001 assets into development, and this would only be achieved through no new DDC funding during that period.



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Key trade-offs with \$500MM Ph. III biased portfolio

Pros

- All Ph III programs are funded.
- Significantly higher expected value than \$500MM phase balanced portfolio
- Higher R&D investment productivity than \$500MM phase balanced portfolio.

Cons

- Significantly under-utilizes pre-Ph. III assets.
- Product launch decline after 2005.
- Results in a mismatch between Discovery output and early development fund availability.
- Internal development of under-utilized 2001 assets will require significant increases in 2002 - 2005 development spending.

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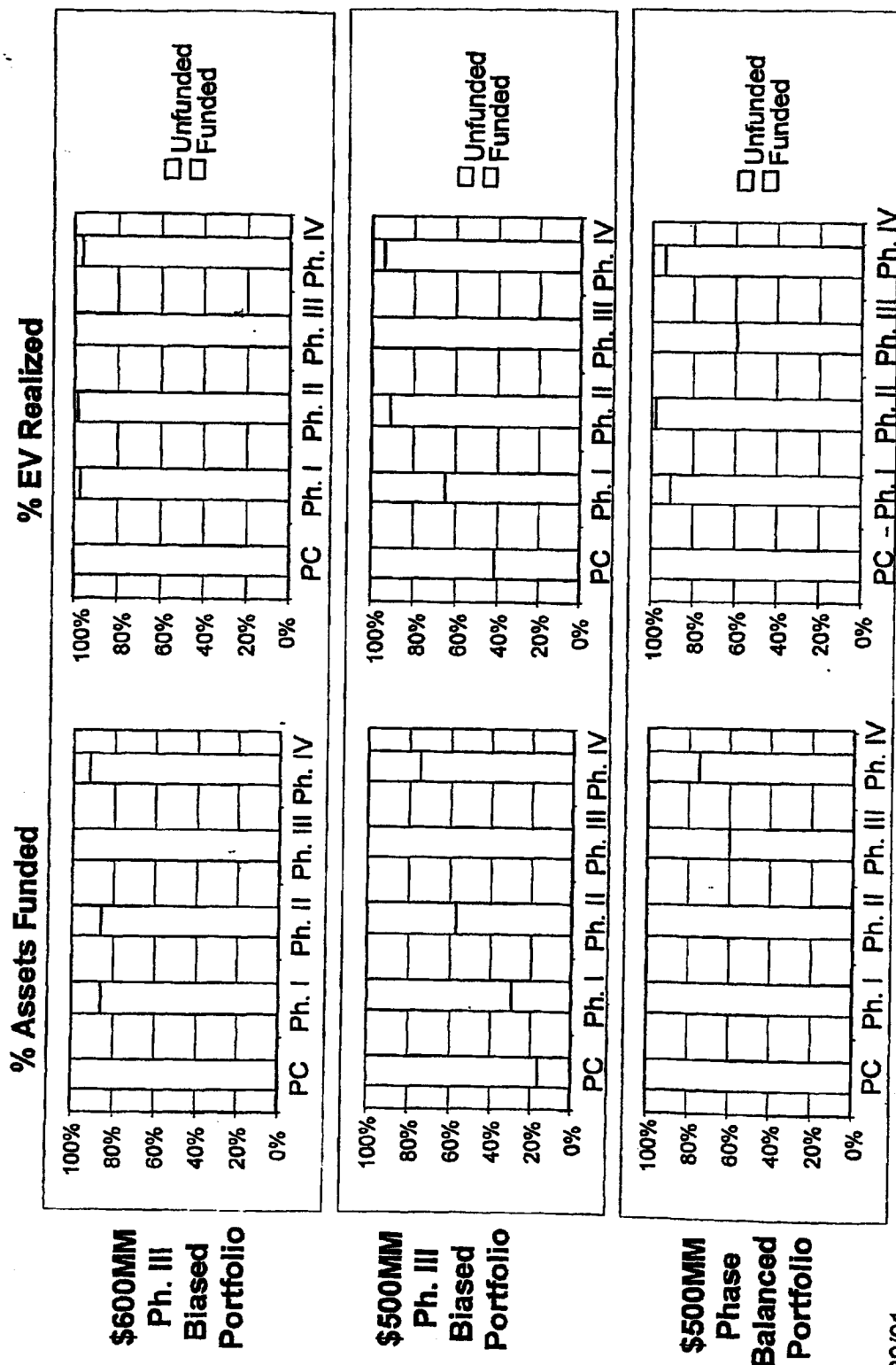
Scenario 3

- **Funding Level: \$600MM**
- **Ph. IV Allocation: 20%**
- **Ph. III Biased Selection (requires all Ph. III projects to be funded)**

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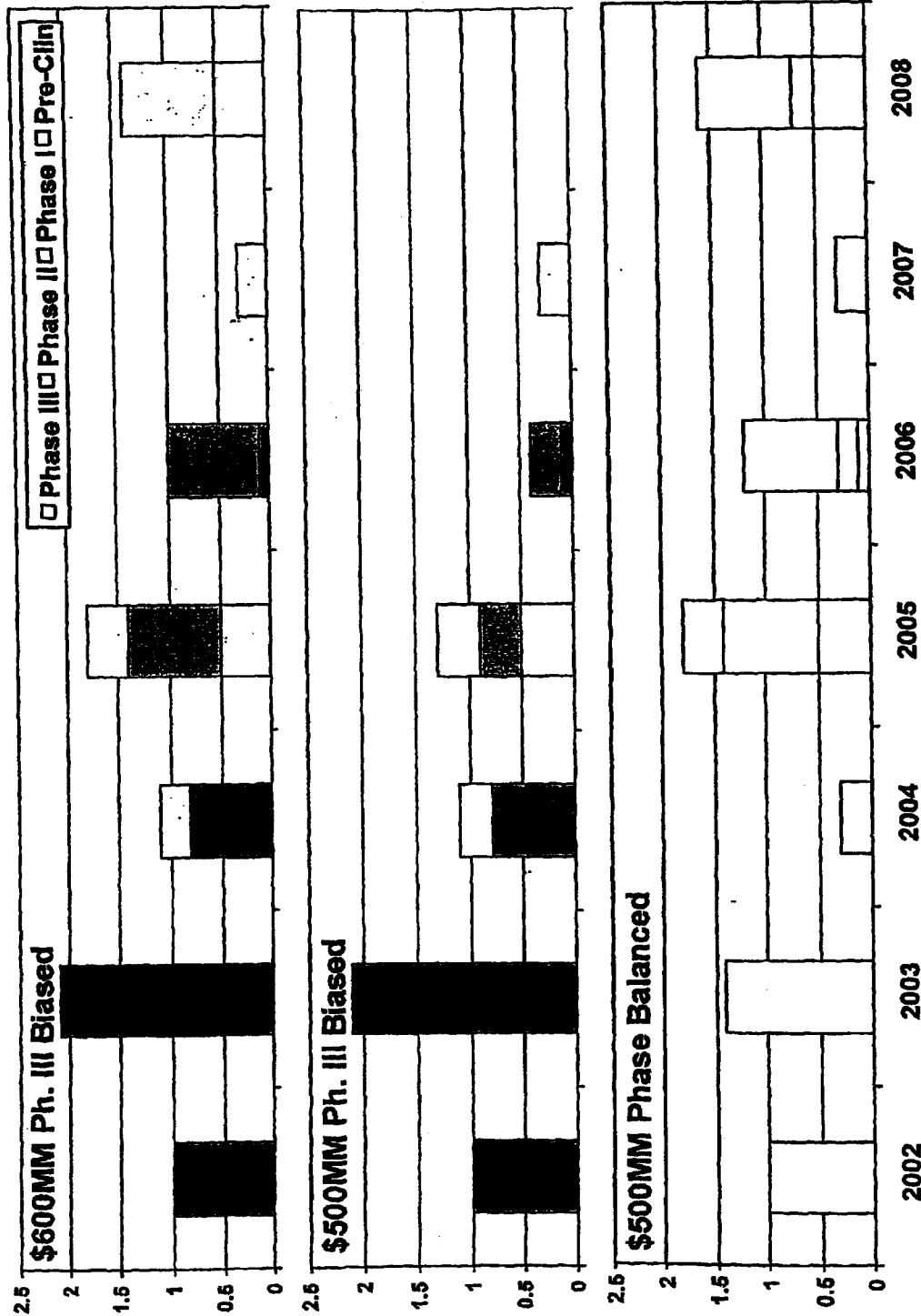
45

The \$600MM Ph. III biased portfolio greatly improves the utilization of pre-Ph. III assets compared with \$500MM.



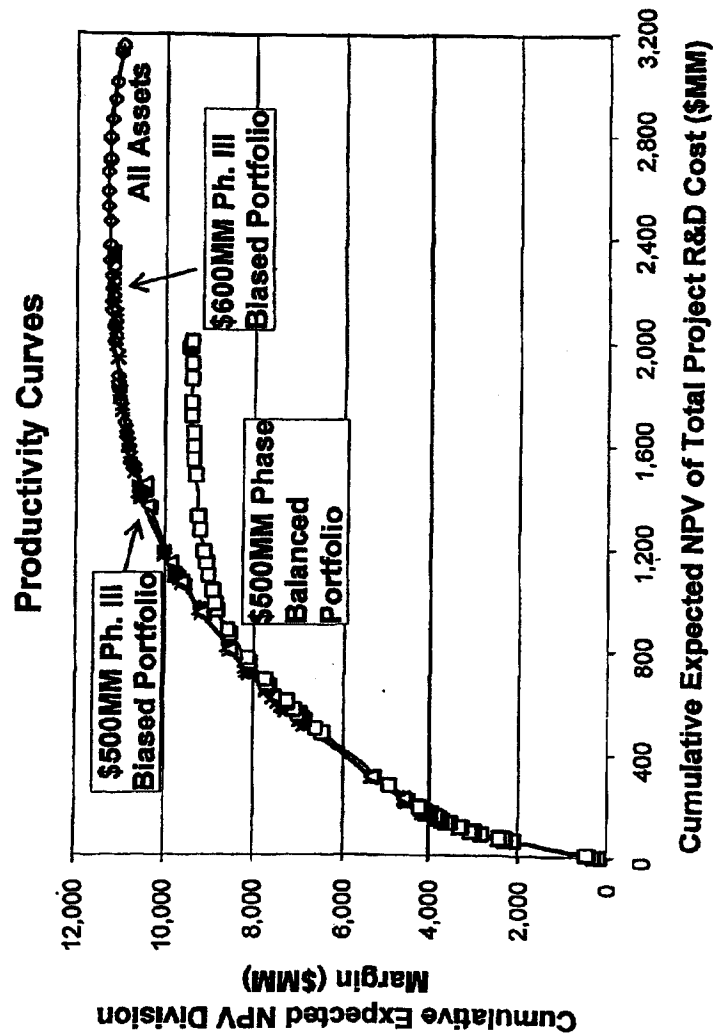
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The improved phase balance of the \$600MM Ph. III bias portfolio ensures consistent product launches through 2008.



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The \$600MM Ph. III biased portfolio realizes almost all of the potential expected value out of our current asset pool.



\$600MM Ph. III Biased:

EV: \$11.1B
PI: 4.8

\$500MM Ph. III Biased:

EV: \$10.4B
PI: 7.2

\$500MM Phase Balanced:

EV: \$9.4B
PI: 4.7

2001 Plan (\$300 MM):

EV: \$4.5B
PI: 4.0

All Assets:

EV: \$11.3B
PI: 4.3

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\$600MM Ph. III Biased / Ph. IV = 20% Program Detail

Pre-clinical	Ph. I	Ph. II	Ph. III	Ph. IV
T4/T3 ABT-598 ABT-828 6 Future DDC's	ABT-963 ABT-510 ABT-751 AU-224: CRC ABT-492 ABT-518	ABT-594 Ganaton PEG Hirudin J695 BSF 190555 BSF 201640 Darusentan	SEGARD ABT-822 D2E7 ABT-627 ABT-773	Clari Kaletra Ritonovir Cilvarine: Hemo Fenofibrate Propafenone SR Gengraf Sibutramine Depakote Other Knoll Ph IV Dilaudid IR & CR Hydrocodone Omnicef
Hokunalin Tape ABT-677	ABT-089 BSF 420627			

Funded

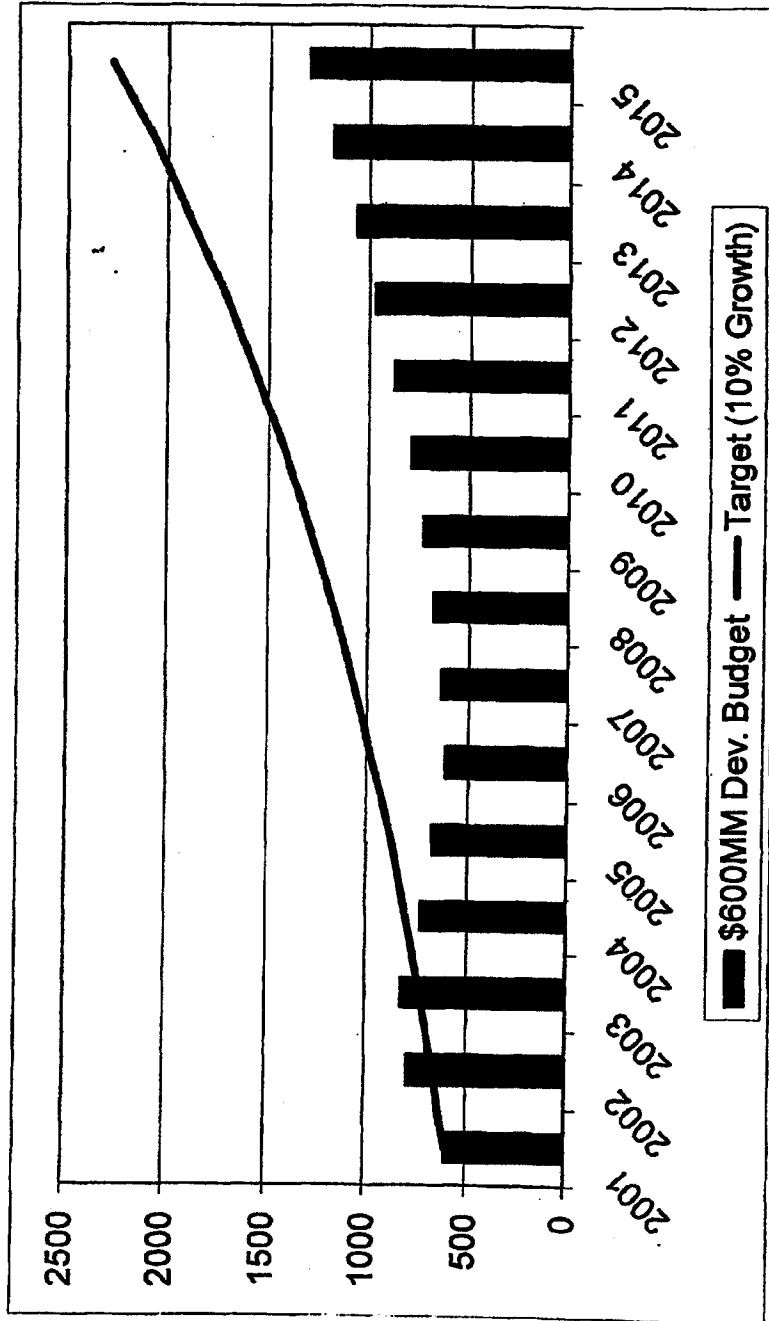
Unfunded

Green: increase to \$500MM Ph. III Biased

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The \$600MM Ph.III bias portfolio will require significant development funding increases in 2002 and 2003, rising to around \$825MM in 2003.



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Key trade-offs with \$600MM Ph. III biased portfolio

Pros

- Realizes almost all of the current asset pool expected value.
- Consistent product launch through 2008.
- Maximum expected value.
- Good match between Discovery output and Development funding capacity.

Cons

- Costs \$600MM in 2001
- Results in significant 2002 – 2004 development expense (peaking at \$825MM in 2003).

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Portfolio Scenario Trade-Off Summary

	Abbott 2001 Plan (\$300MM)	Abbott / Knoll Development Portfolio		
		\$500MM Phase Balanced	\$500MM Ph. III Bias	\$600MM Ph. III Bias
Expected Value	\$4.5 B	\$9.4 B	\$10.4 B	\$11.1 B
R&D Productivity	4.0	4.7	7.2	4.8
Pre-Ph.III Asset Utilization	Poor	Good	Poor	Good
Product Launch Consistency	Post 2005 decline	Consistent through 2008	Post 2005 decline	Consistent through 2008
2002-2004 R&D Cost Implications	Within 10% growth target	Within 10% growth target	Within 10% growth target	Significant
Other Issues	Productive Ph.IV programs not funded	Key Ph.III Programs Not Affordable	Utilization of unfunded 2001 assets	Development budget rises to \$825MM by 2003

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BACKUPS

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ABBT127610.UR

2001-2002 R&D Costs for John Hancock Compounds

Compounds	2001 Costs (\$MM)	2002 Costs (\$MM)	
		Nominal	Expected
ABT-773 Ketolide Tablet	88.0	61.3	61.3
ABT-773 Ketolide IV	7.5	8.8	4.4
ABT-627 Endothelin	41.8	50.0	50.0
ABT-594 Neuro Pain	17.2	58.4	26.3
ABT-510 TSP	10.5	22.5	19.1
ABT-492 Quinolone Tablet	21.5	67.7 (1)	48.7
ABT-518 MMPi	9.4	38.1	28.6
ABT-751 Anti-Mitotic	8.4	31.1 (2)	12.4
ABT-XXX FTI	2.0	15.0	9.4
ABT-XXX Dopamine Receptor Agonist	6.0	15.0 (3)	9.4
Total	212.3	367.9	269.6

Blue Text signifies unfunded programs in the \$500MM Phase Balanced Ph IV 20% portfolio.

Green Text signifies programs funded in each portfolio.

Red Text signifies unfunded programs in the \$500MM PhIII Bias Ph IV 20% portfolio.

All Hancock programs funded in the \$600MM PhIII Bias Ph IV 20% portfolio.

(1) ABT-492 expense excludes \$5MM milestone payment to Wakunaga.

(2) ABT-751 expense excludes \$2MM milestone payment to Eisai.

(3) Dopamine Receptor Agonist uses Abbott historical development costs and assumes initiation of Phase I in 2Q02.

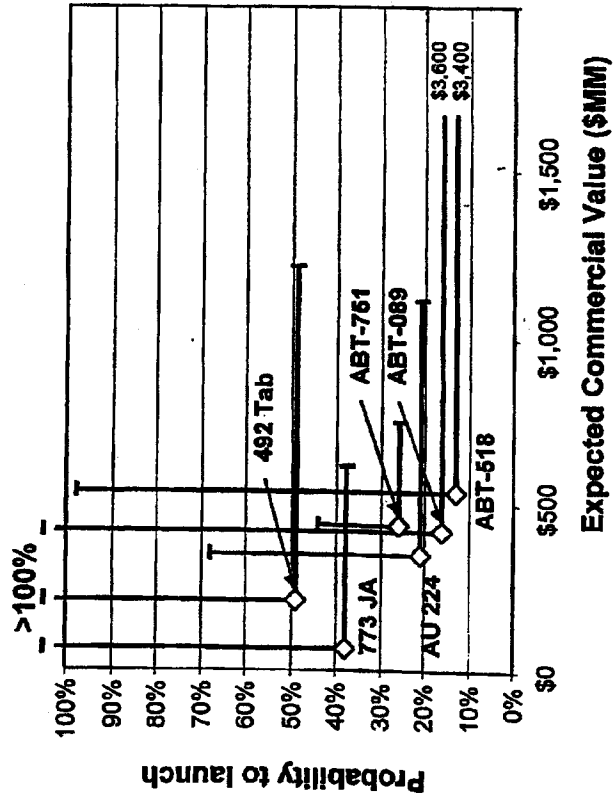
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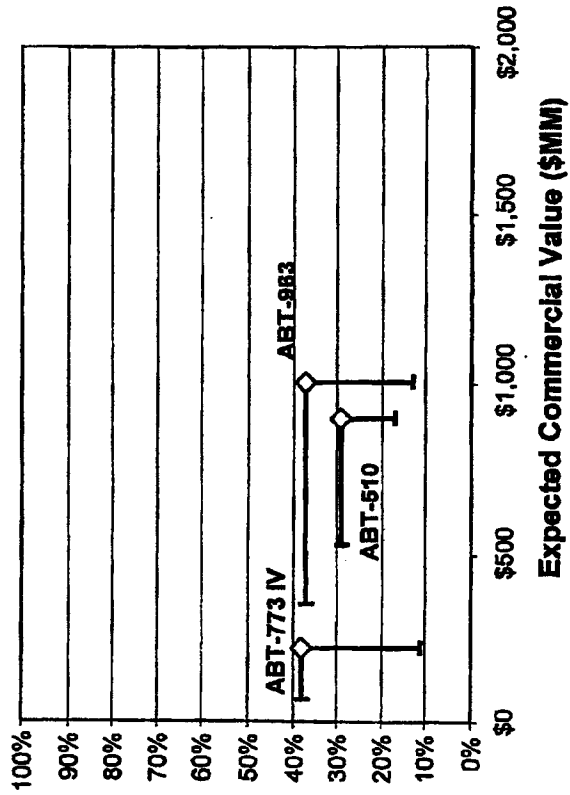
Phase I projects

**\$500MM
Phase III Bias
20% Phase IV**

Projects out of portfolio



Projects in portfolio



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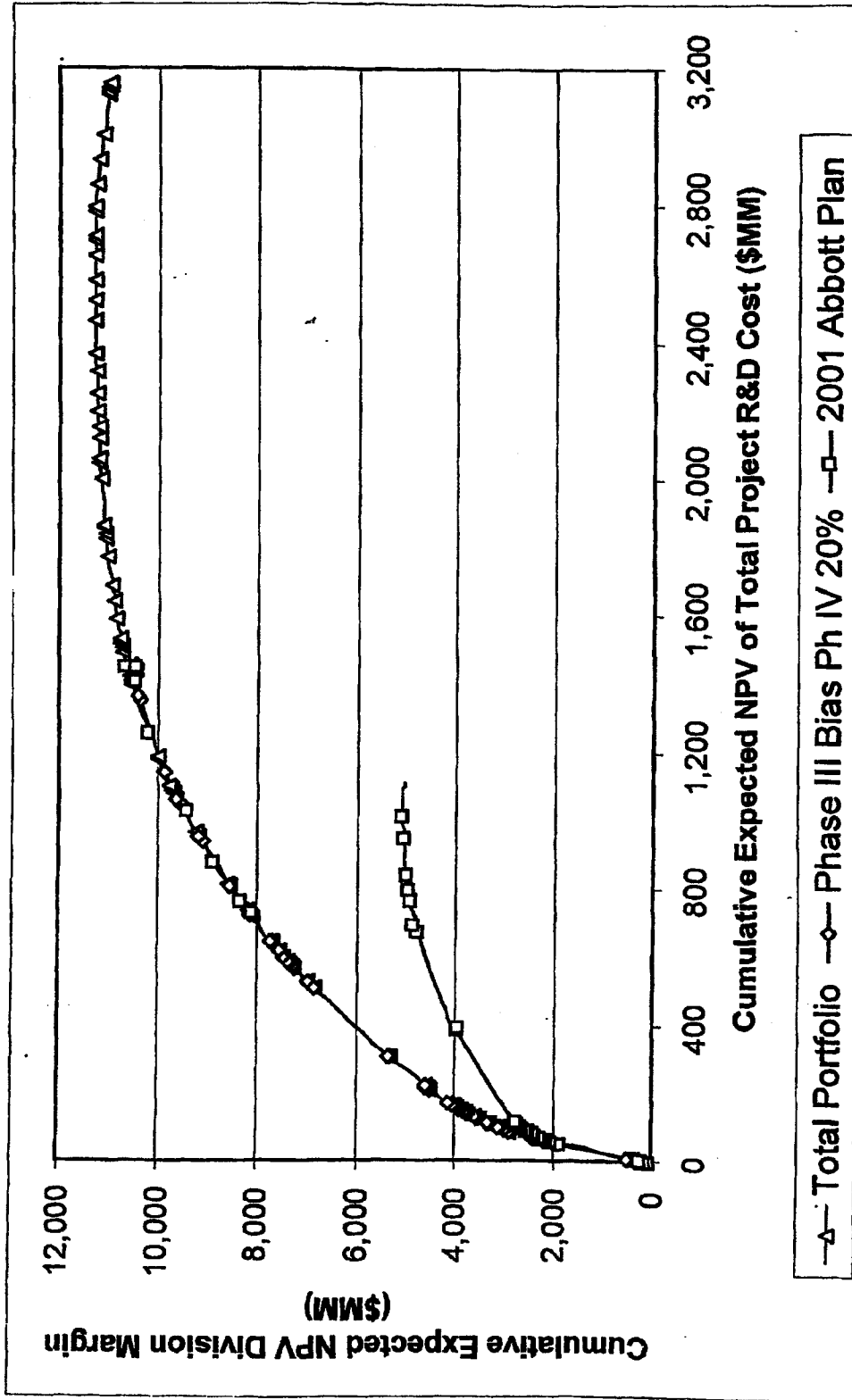
2001 Costs Assuming Project Discontinuation in May '01

(\$ Millions)	\$500MM Phase Balanced	\$500MM Phase Biased	\$600MM Phase Biased
ABT-773	60
ABT-627	15
Darusentan	...	10	10
ABT-492	...	9	...
Sibutramine: Japan	7	7	7
ABT-518	...	5	...
ABT-751	...	4	...
Depakote: Elderly Agitation	2	2	2
Sibutramine: Binge & Bulimia	2	2	2
AU-224	...	2	...
Omnicef: Otitis Media	...	2	2
Depakote: ER 250mg	1	1	1
Gengraf: PREFER	1	1	1
ABT-089	...	1	1
BSF 201640	n/a	n/a	...
Clivarine: Cardio	n/a	n/a	n/a
Dilaudid	n/a	n/a	...
Hydrocodone	n/a	n/a	n/a
Total	88	46	26

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Value added from 2001 Abbott Plan



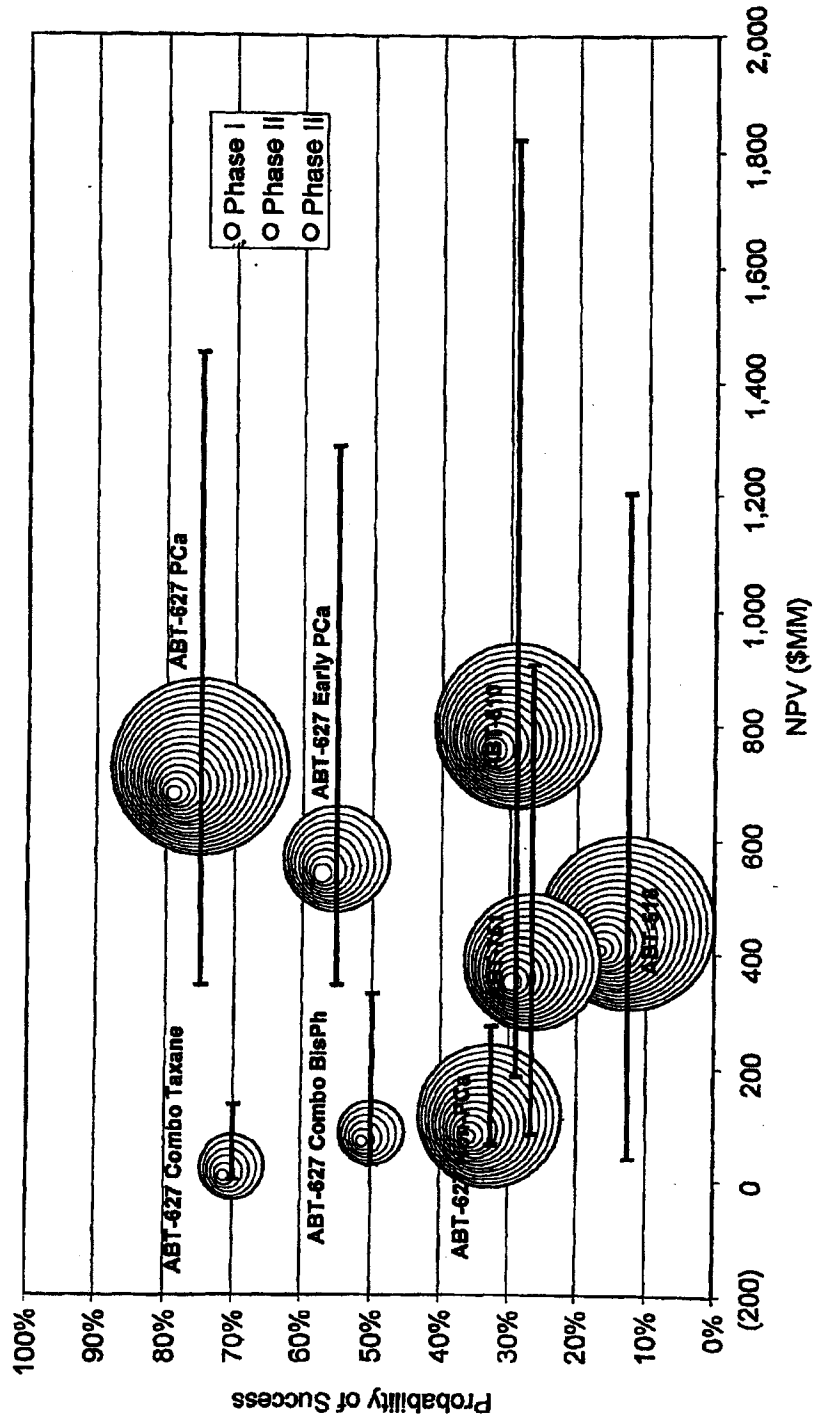
◆ Signifies Knoll projects

□ Signifies Abbott 2001 Plan projects that are now unfunded in the Ph III bias Ph IV 20% portfolio

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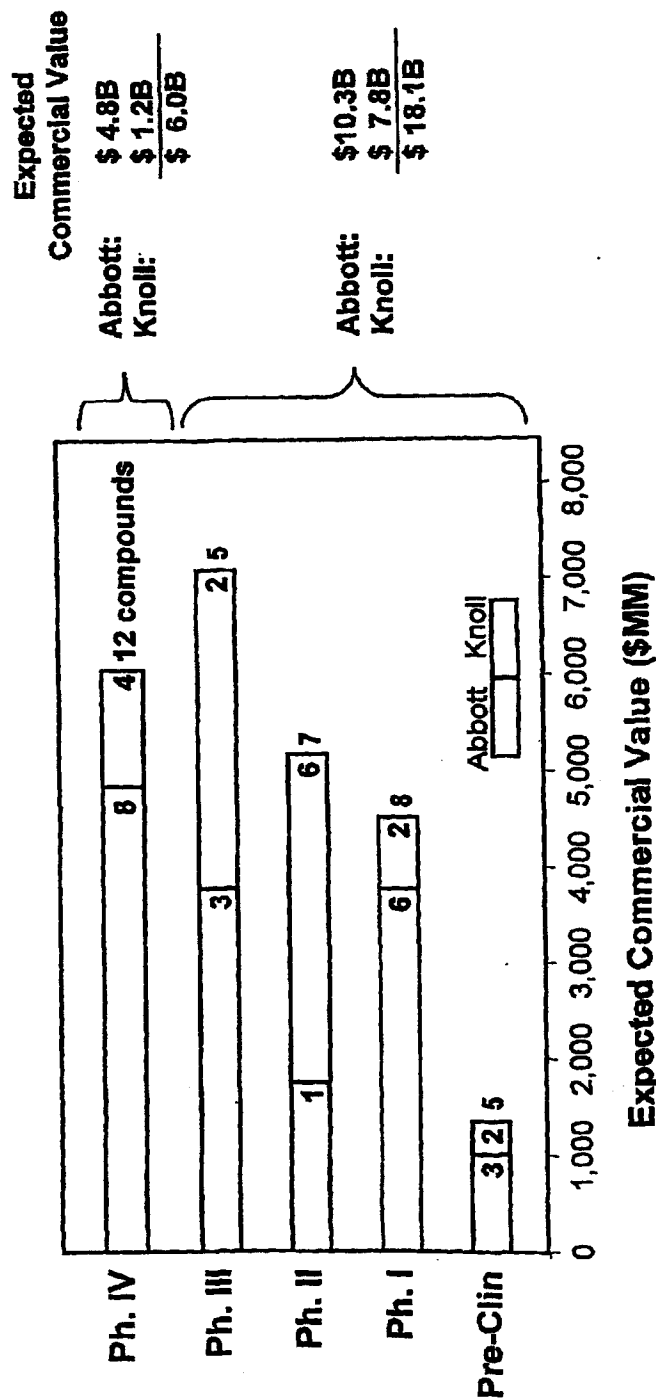
Oncology



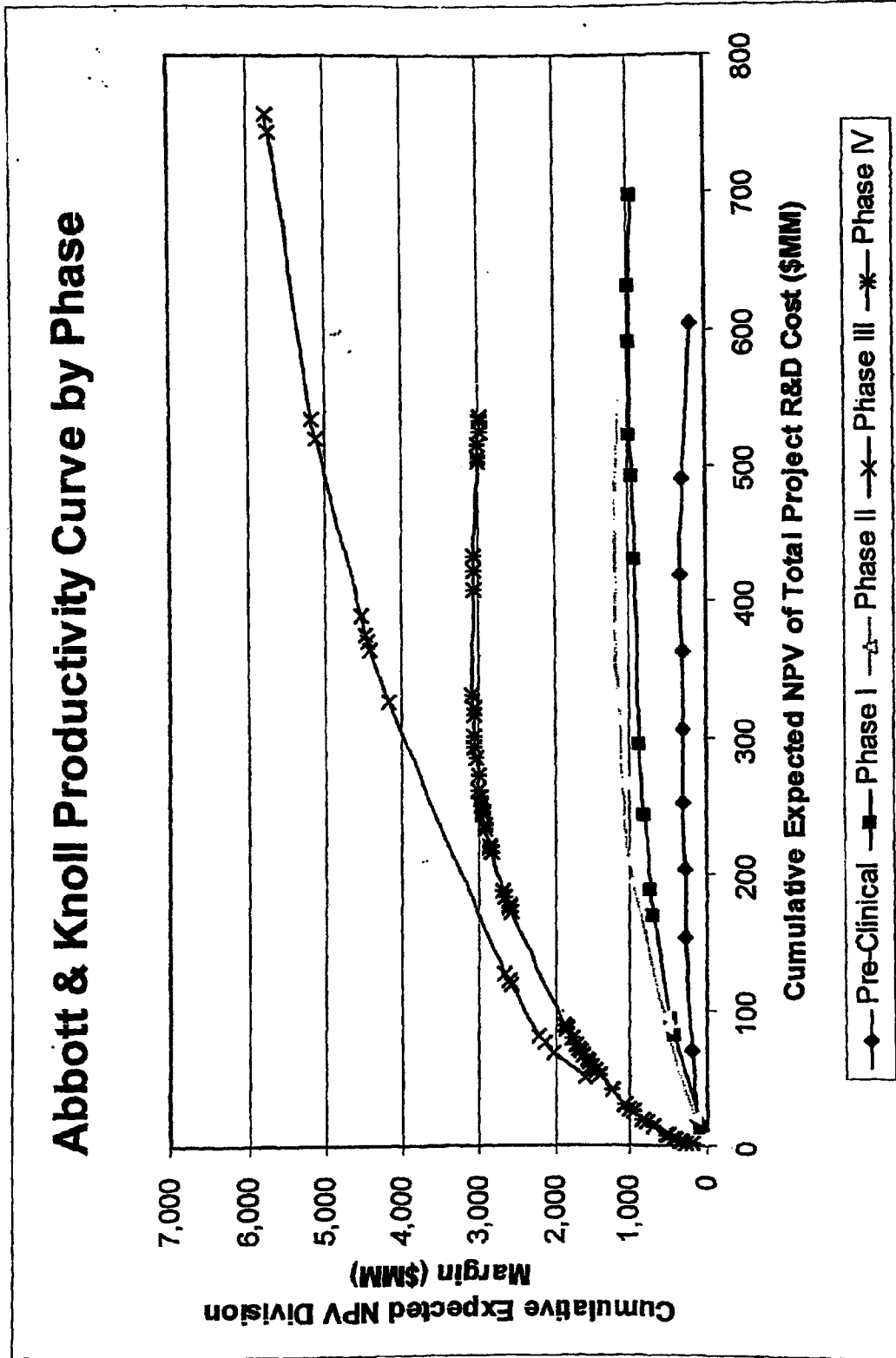
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Abbott and Knoll contributions to the total asset pool differ by current phase of development.

- Knoll-originated programs contribute most prominently in Ph. II and Ph. III.
- Pipeline programs (DDC-Ph. III) provide approximately 75% of overall expected commercial value and about 50% of total compounds.



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Pipeline by Therapeutic Area (1)

	Pre-Clinical	Phase I	Phase II	Phase III	Marketed Products (Ph. IV)
Anti-Infective	• ABT-677	• ABT-492		<ul style="list-style-type: none"> • Kaletra • ABT-773 	<ul style="list-style-type: none"> • Kaletra • Ritonavir • Clarithromycin • Omnicef
Cardiovascular/ Thrombosis			<ul style="list-style-type: none"> • Darusentan 		<ul style="list-style-type: none"> • Fenofibrate • Propafenone(Rhythmol) • Cilvarine
Gastrointestinal		• AU-224	• Ganaton		
Immunoscience		• Hokunalin Tape	• J695	<ul style="list-style-type: none"> • D2E7 • SEGARD 	<ul style="list-style-type: none"> • Gengraf
Metabolic Diseases	• T4/T3		• ABT-822		<ul style="list-style-type: none"> • Sibutramine • Synthroid

Abbott programs in blue; Knoll programs in red

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Pipeline by Therapeutic Area (2)

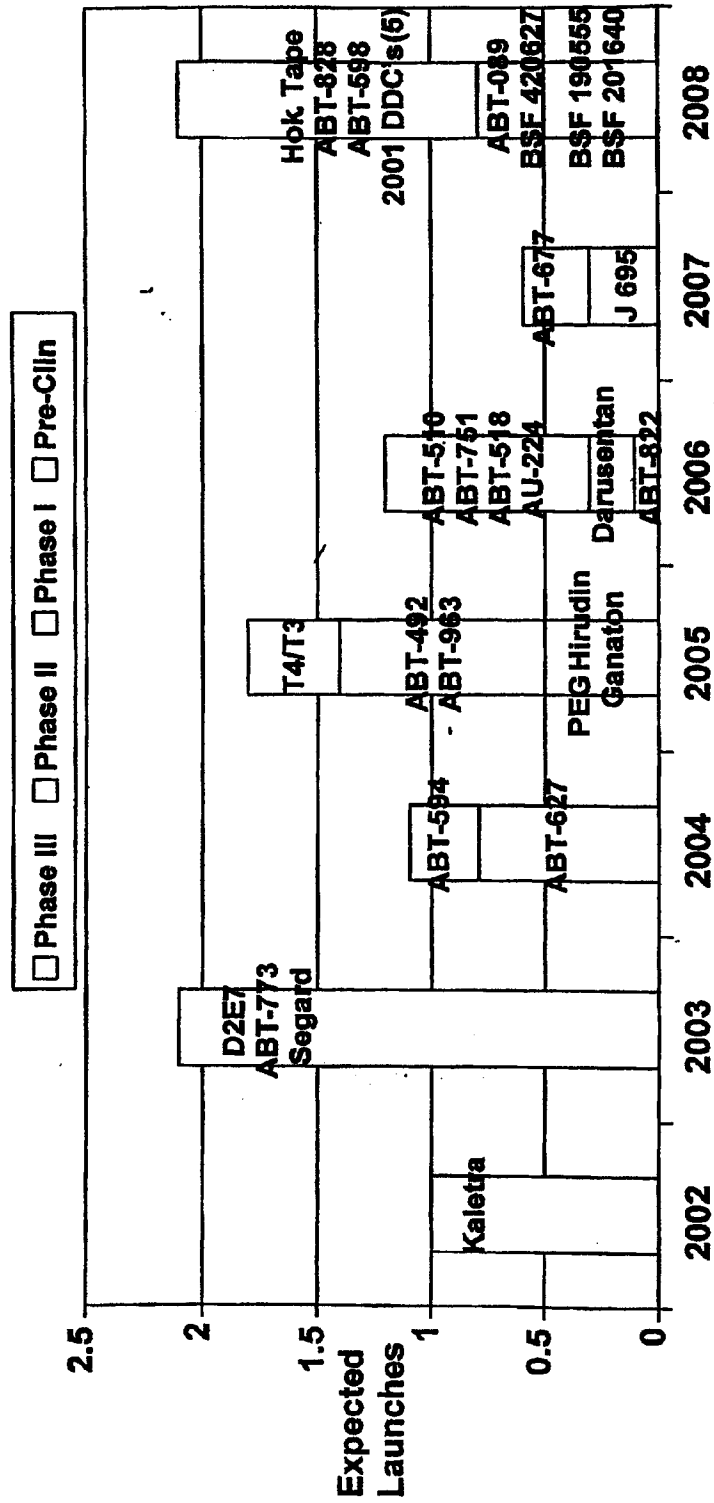
	Pre-Clinical	Phase I	Phase II	Phase III	Marketed Products (Ph. IV)
Neuroscience		<ul style="list-style-type: none"> • ABT-089 	<ul style="list-style-type: none"> • BSF201640 • BSF190555 		<ul style="list-style-type: none"> • Depakote
Oncology	<ul style="list-style-type: none"> • ABT-828 	<ul style="list-style-type: none"> • ABT-518 • ABT-510 • ABT-751 	<ul style="list-style-type: none"> • ABT-627 (non-PCA) 	<ul style="list-style-type: none"> • ABT-672 (PCA) 	
Pain		<ul style="list-style-type: none"> • ABT-963 	<ul style="list-style-type: none"> • ABT-594 		<ul style="list-style-type: none"> • Hydrocodone/bupropfen • Dilaudid • Vicoprofen?
Renal Care			<ul style="list-style-type: none"> • PEG Hirudin 		
Urology	<ul style="list-style-type: none"> • ABT-598 				

Abbott programs in blue; Knoll programs in red

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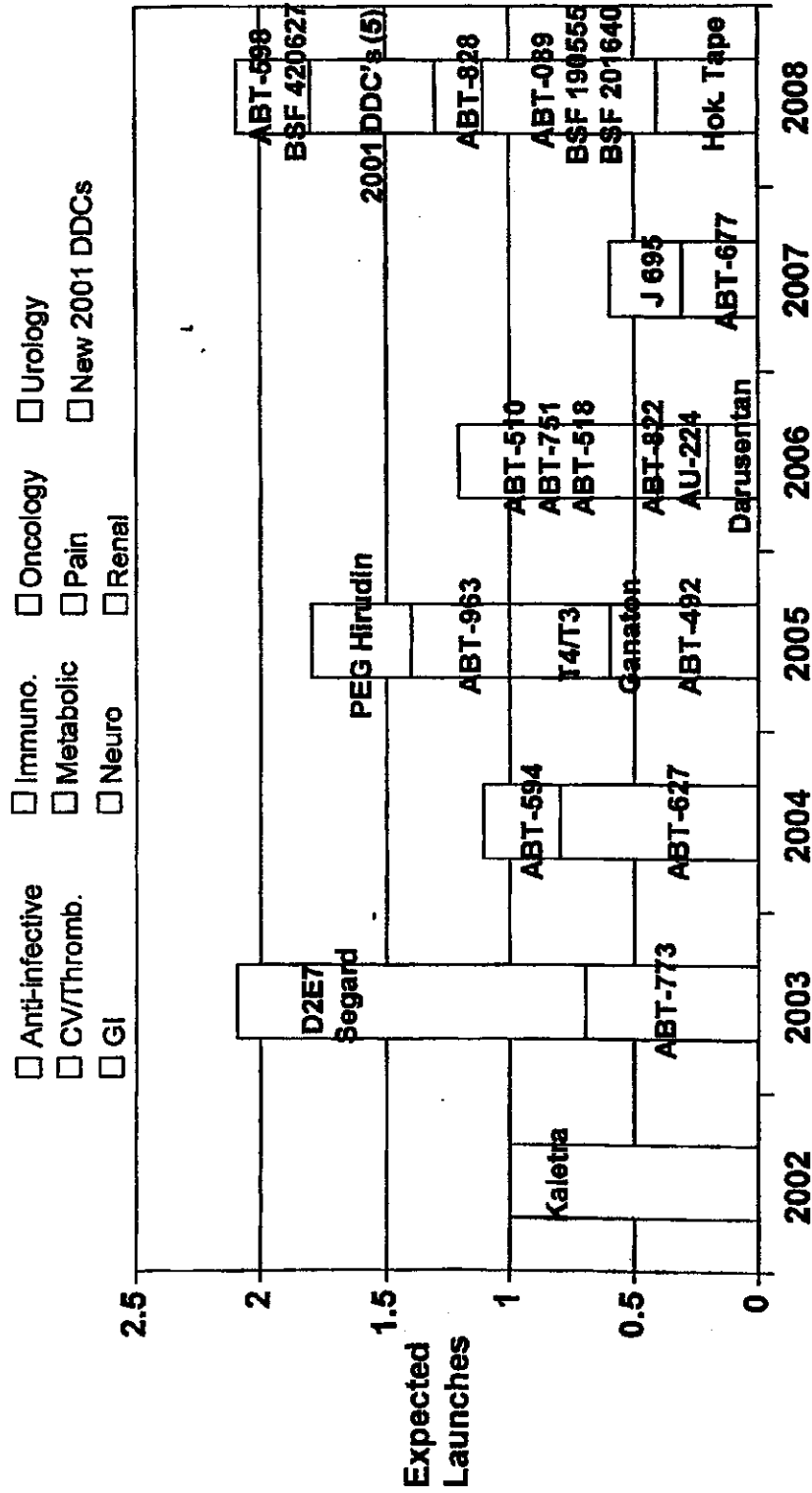
62

Expected Launches by Current Phase of Development



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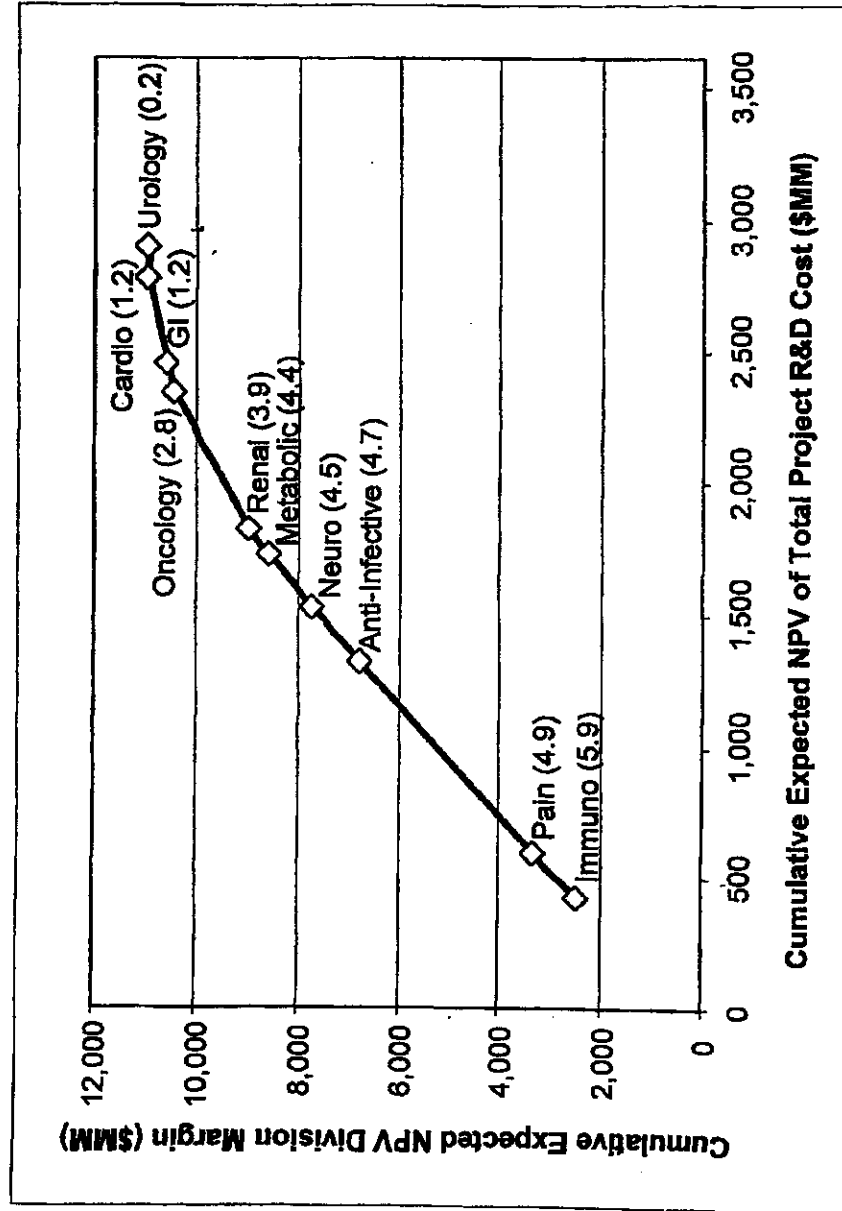
Expected Launches by Therapeutic Area



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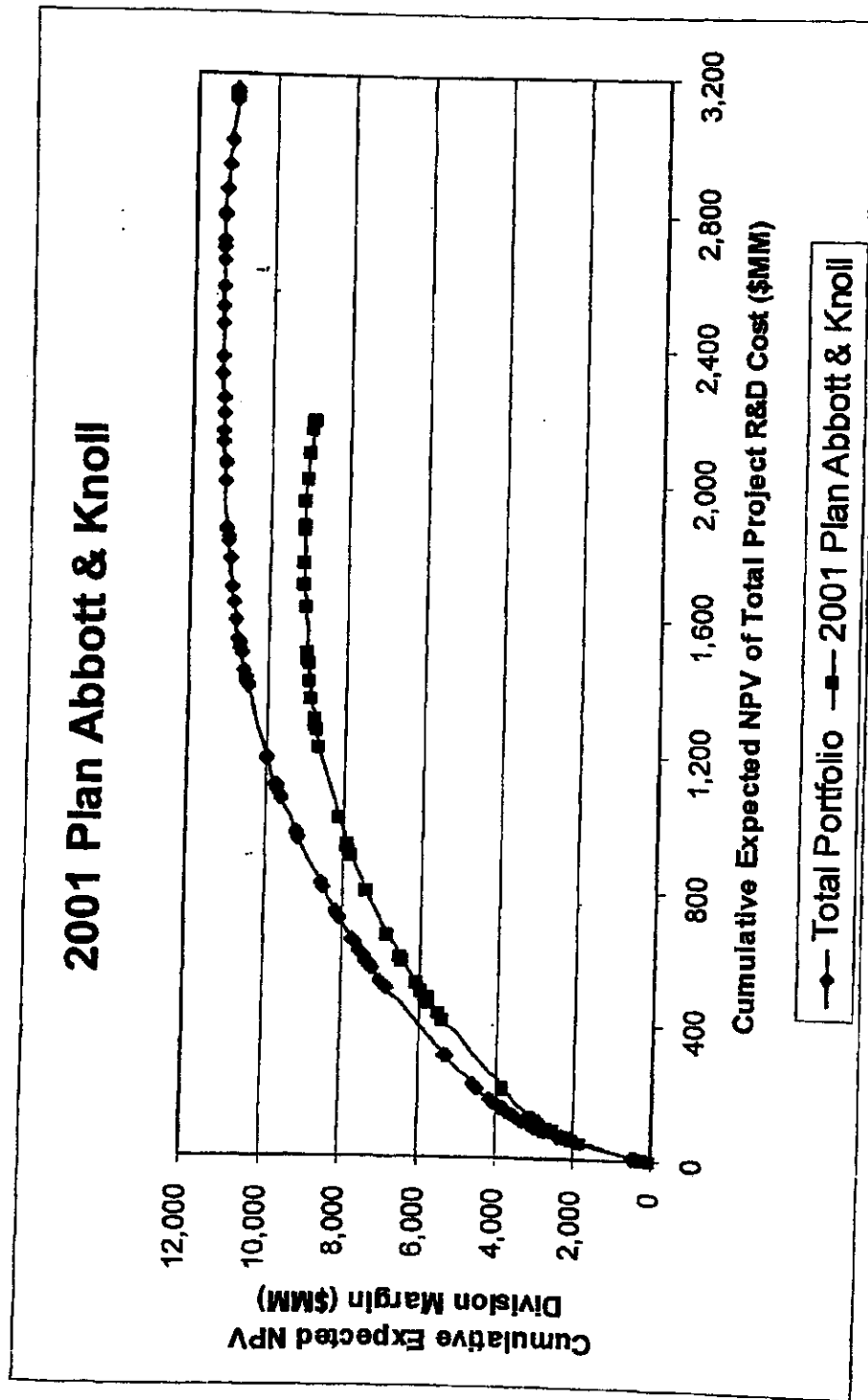
Productivity reflects the overall phase mix of the therapeutic area portfolio.



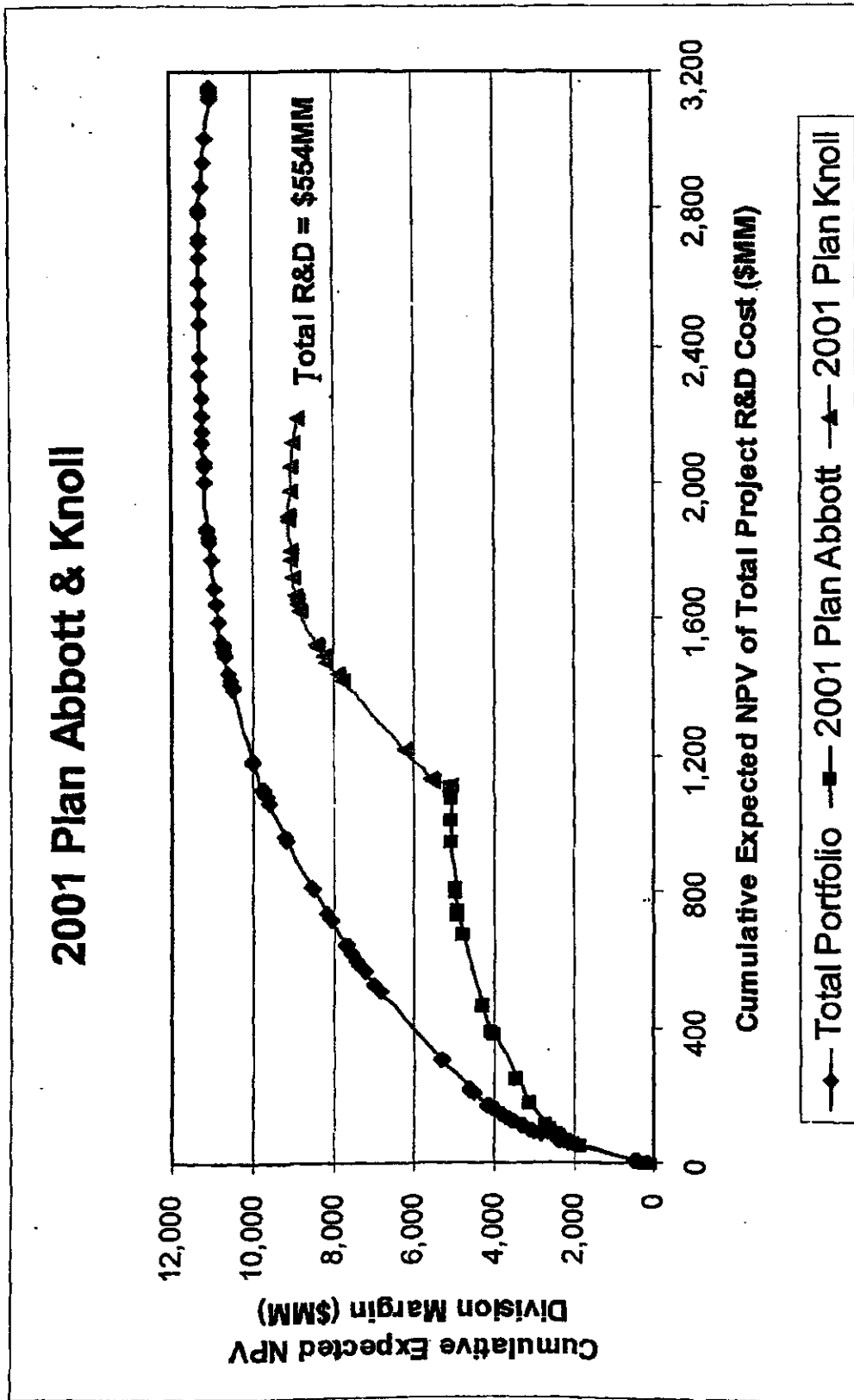
4/20/01

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Productivity curve comparisons – 2001 plan



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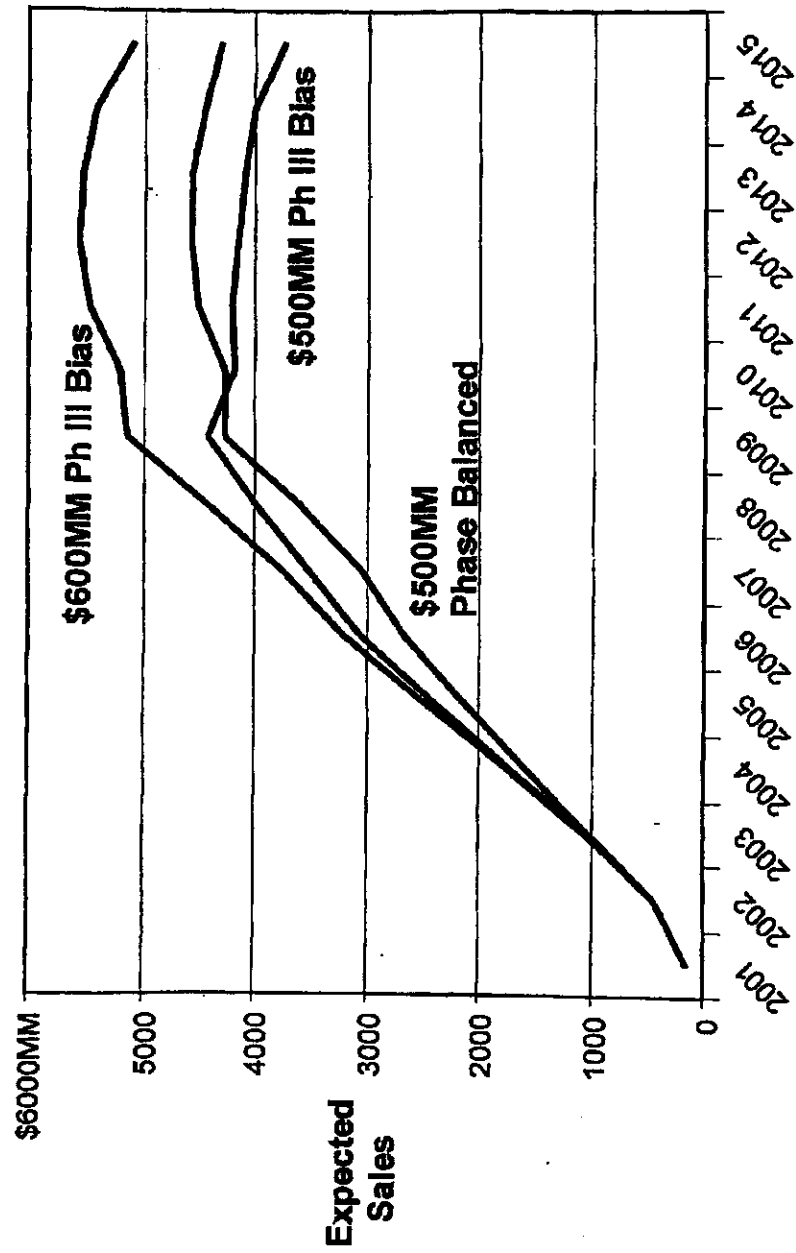
\$500 Million Phase Balanced / Phase IV = 20% Program Detail

Pre-clinical	Ph. I	Ph. II	Ph. III	Ph. IV
Funded T4/T3 ABT-598 ABT-828 5 Future DDC's	ABT-963 ABT-510 ABT-751 AU-224: CRC ABT-492 ABT-089 ABT-518	ABT-594 Ganaton PEG Hirudin J695 BSF 190555 BSF 201640 Darusentan	SEGARD ABT-822 D2E7	Clari Kaletra Ritonovir Clivarine: Hemo Fenofibrate Propafenone SR Gengraf Sibutramine Depakote Other Knoll Ph IV
Unfunded Hokunalin Tape ABT-677	BSF 420627		ABT-627 ABT-773	Dilaudid IR & CR Hydrocodone Omnicef

4/20/01

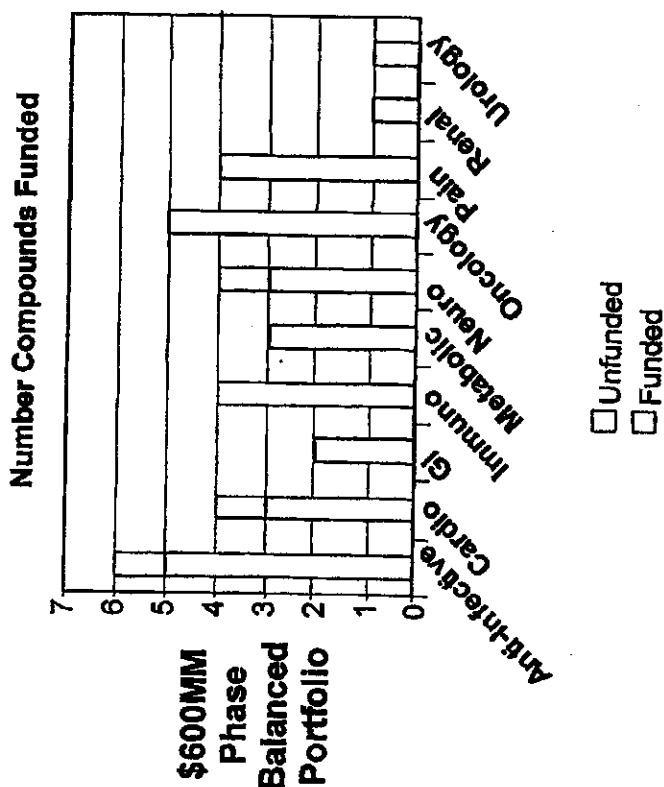
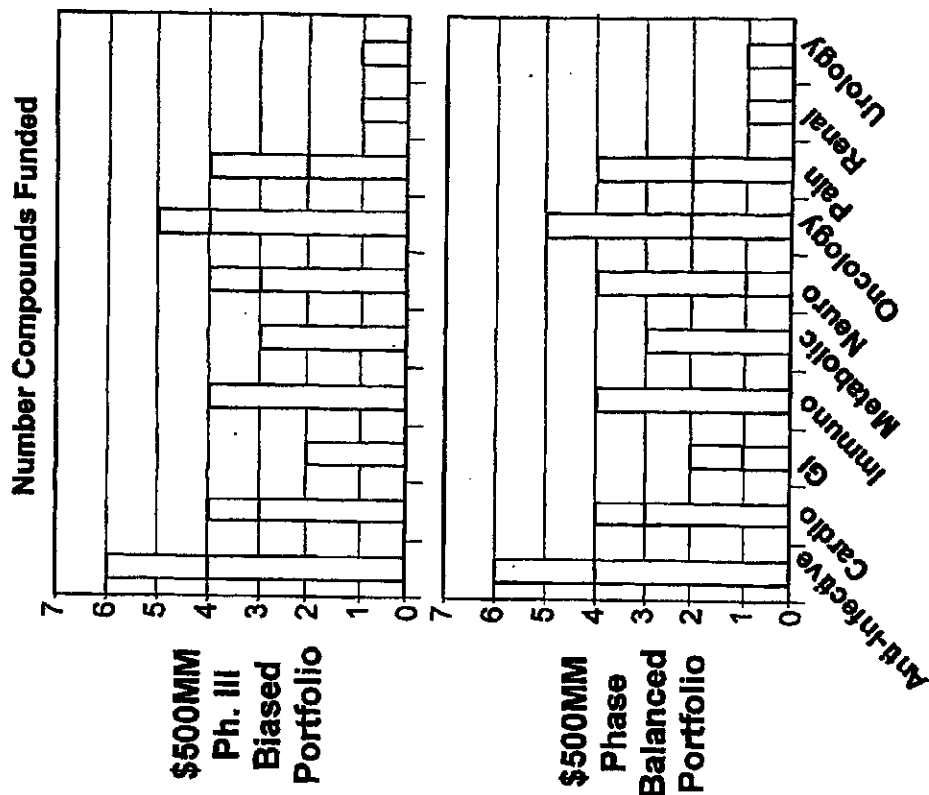
68

Expected sales comparisons



4/20/01

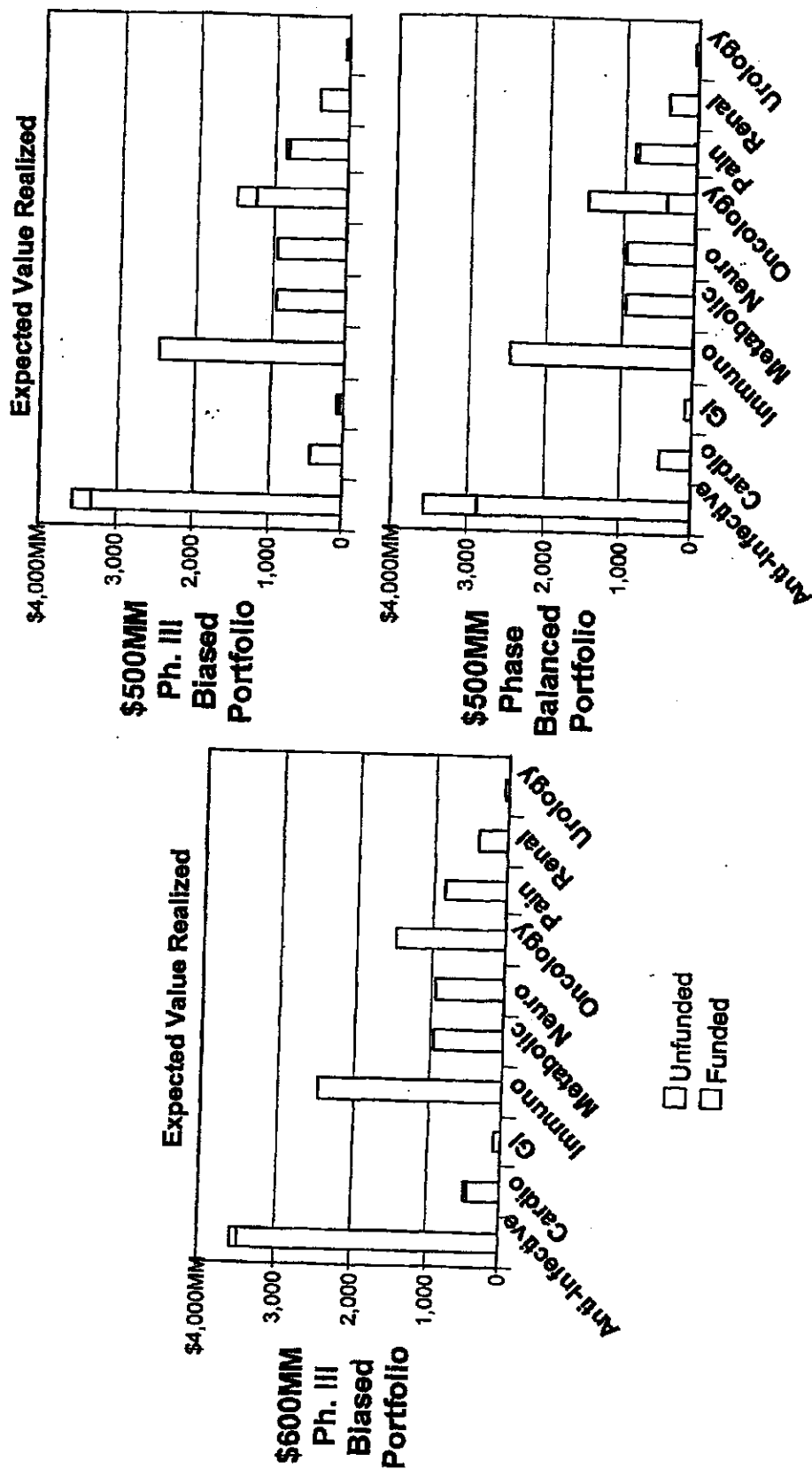
The Ph. III biased portfolio favors therapeutic areas with more a mature asset mix.



4/20/01

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The Ph. III biased portfolio favors therapeutic areas with more a mature asset mix.



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Phase III Biased Portfolio Selection - \$600MM, 20% P4

% Funding by Phase (PC - Ph III)				
Target				
9%	14%	40%		37%
\$600MM Ph. III Biased Portfolio				
7%	16%	14%		64%
\$500MM Ph. III Biased Portfolio				
5%	15%			77%
2%				
\$500MM Phase Bal. Portfolio				
9%	20%	24%		48%

☐ PC
 ☐ Ph I
 ☐ Ph II
 ☐ Ph III

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April 20, 2001

Appendix

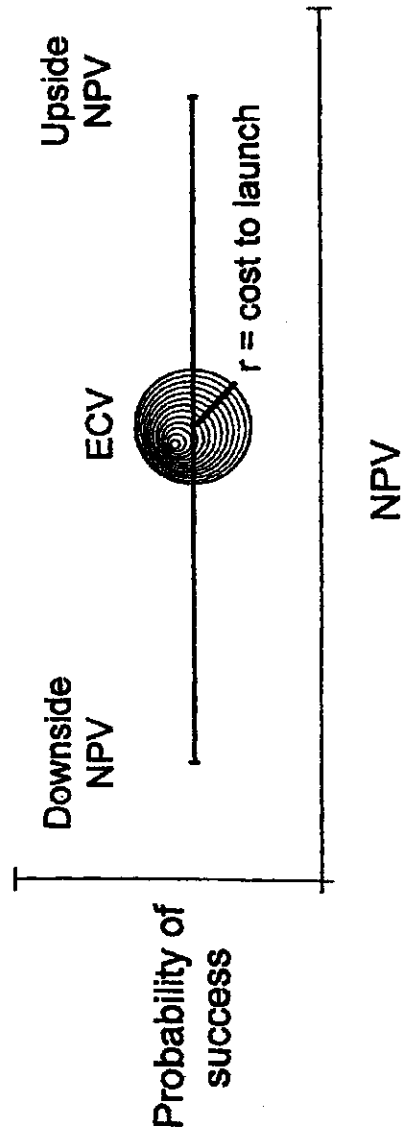
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ABBT127630.UR

Project Attributes by Therapeutic Area

- Project attributes displayed include:
 - Expected commercial value (ECV)
 - Nominal R&D costs to launch
 - Upside and downside NPV assessment assuming launch

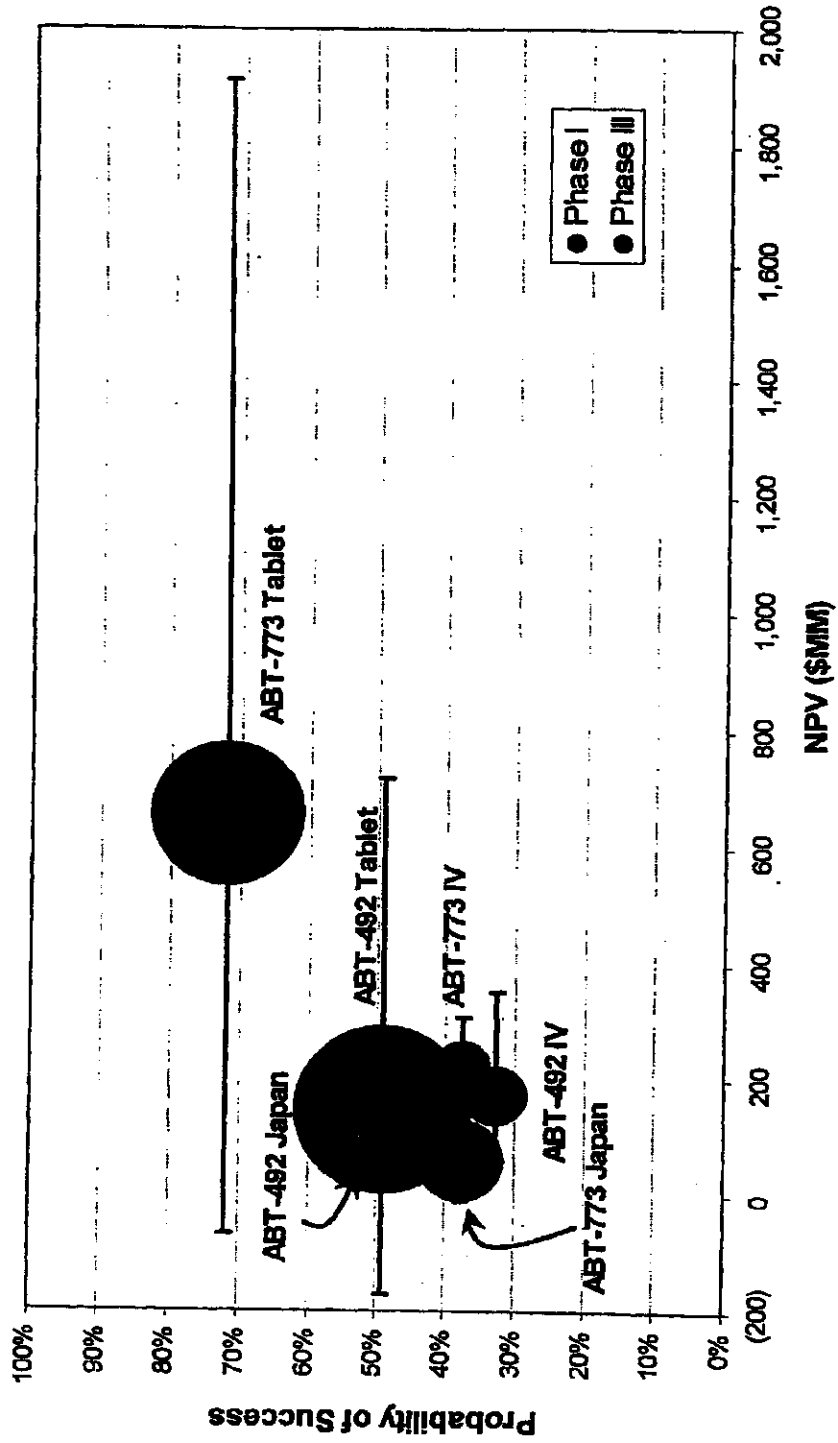


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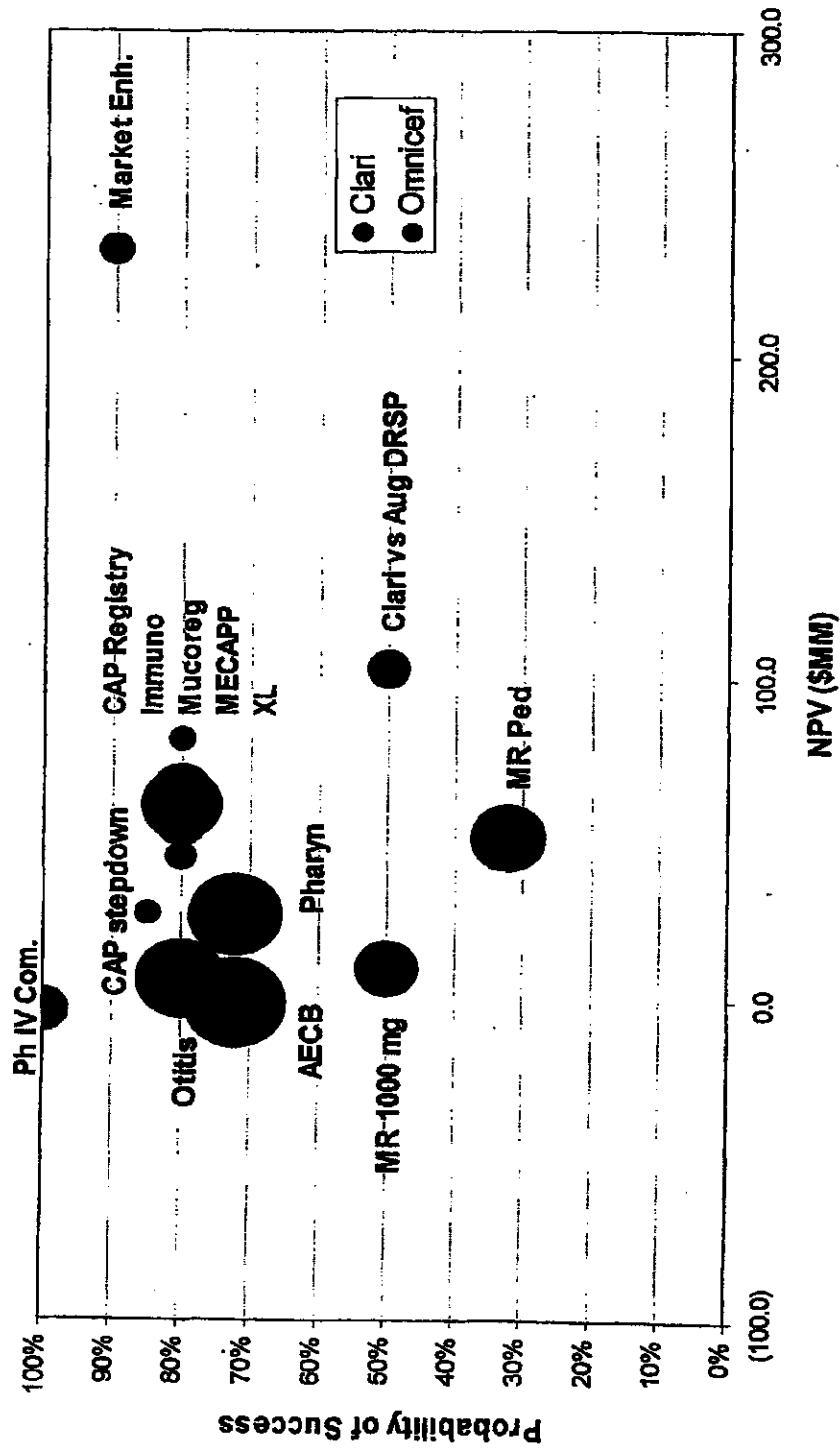
Anti-infectives – Pipeline



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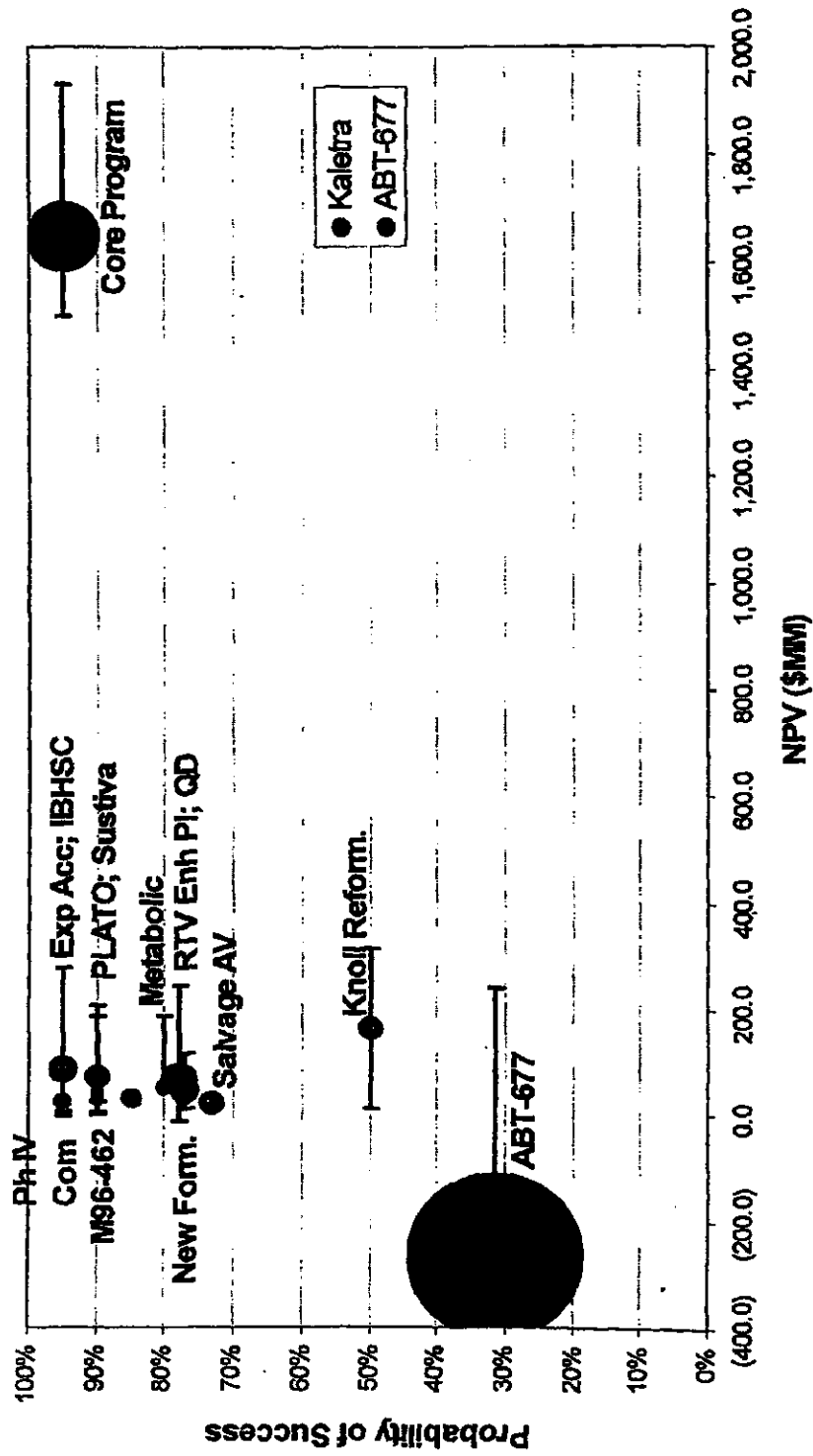
75

Anti-infectives – Phase IV



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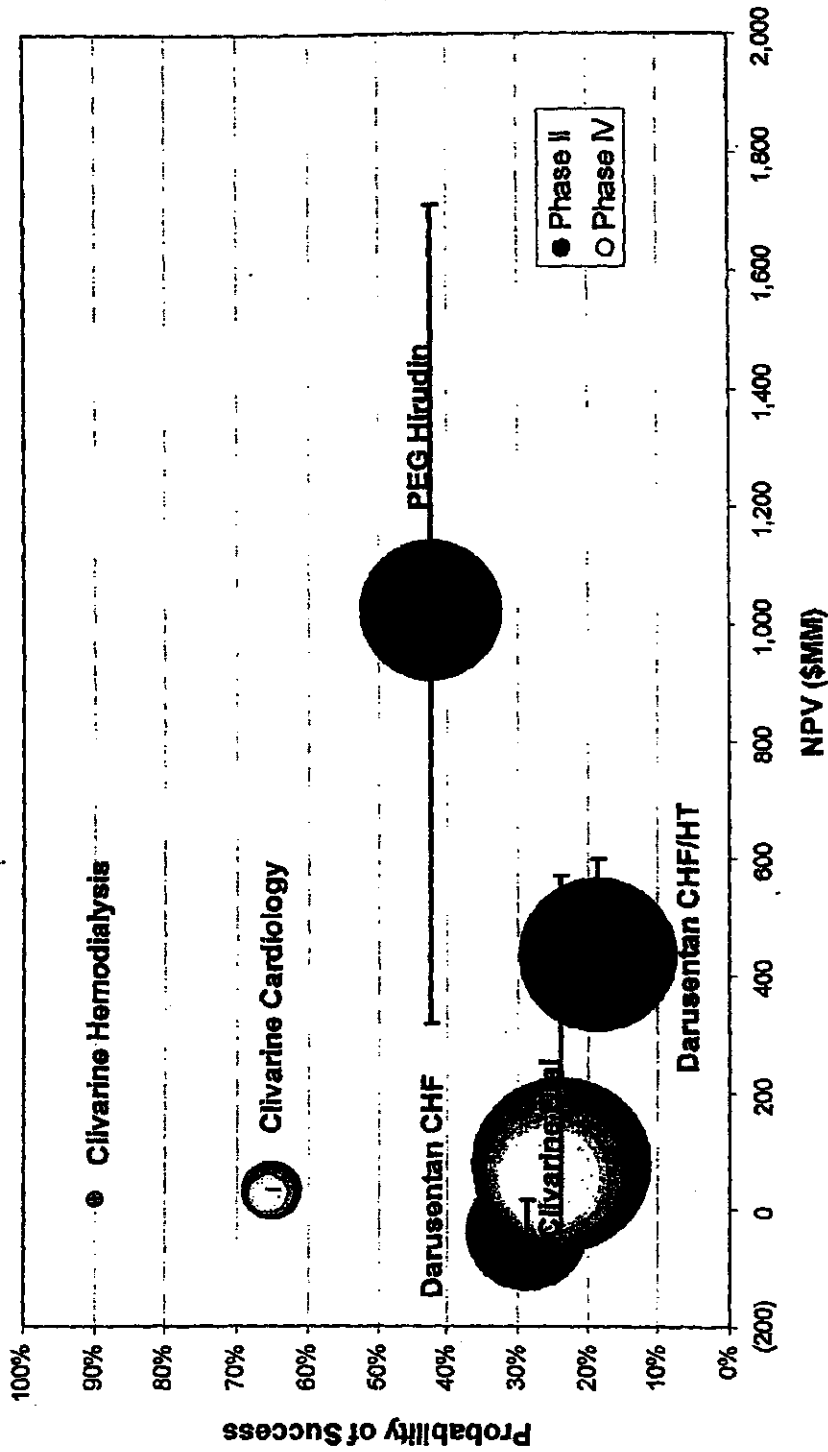
Anti-infectives (Anti-viral)



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77

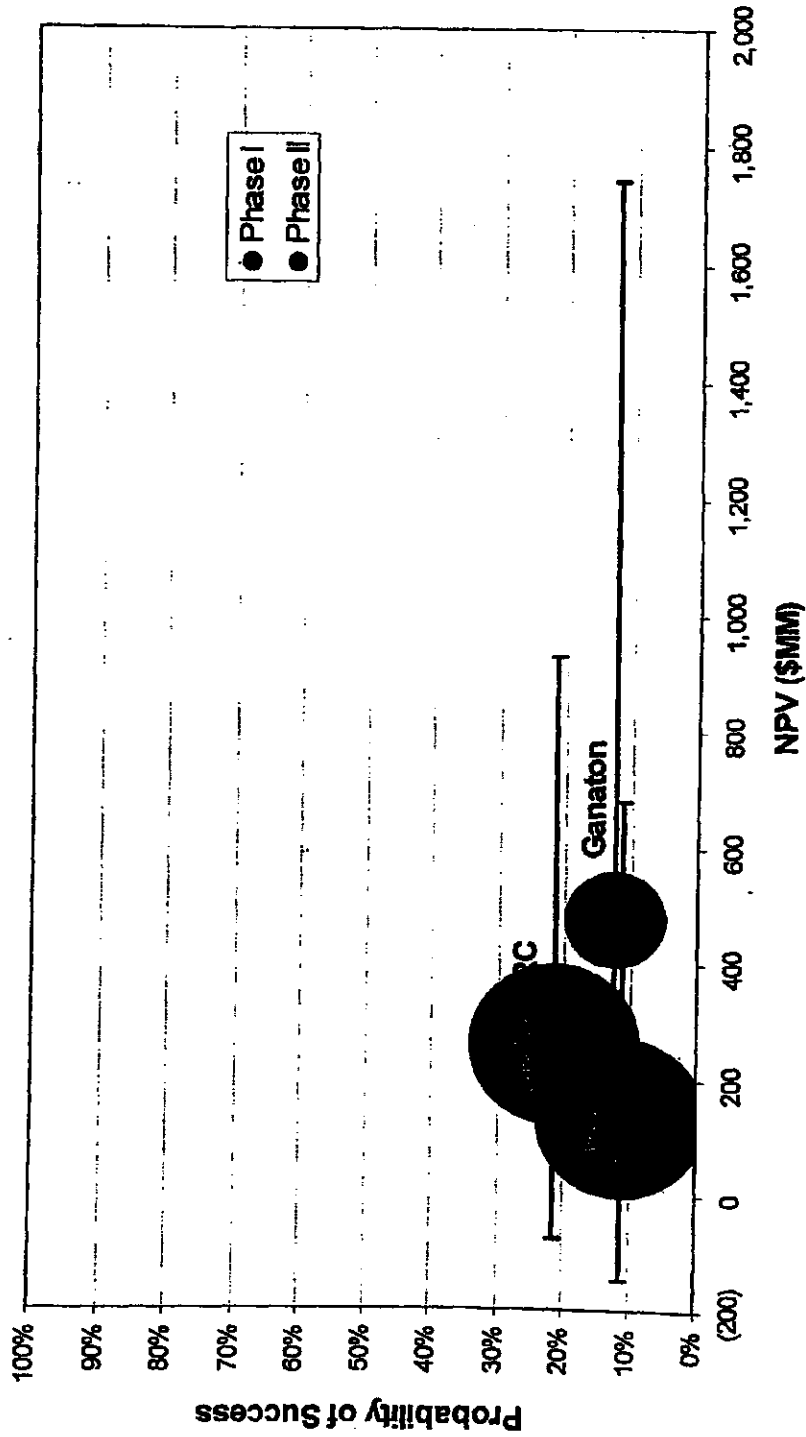
Cardiovascular



4/20/01

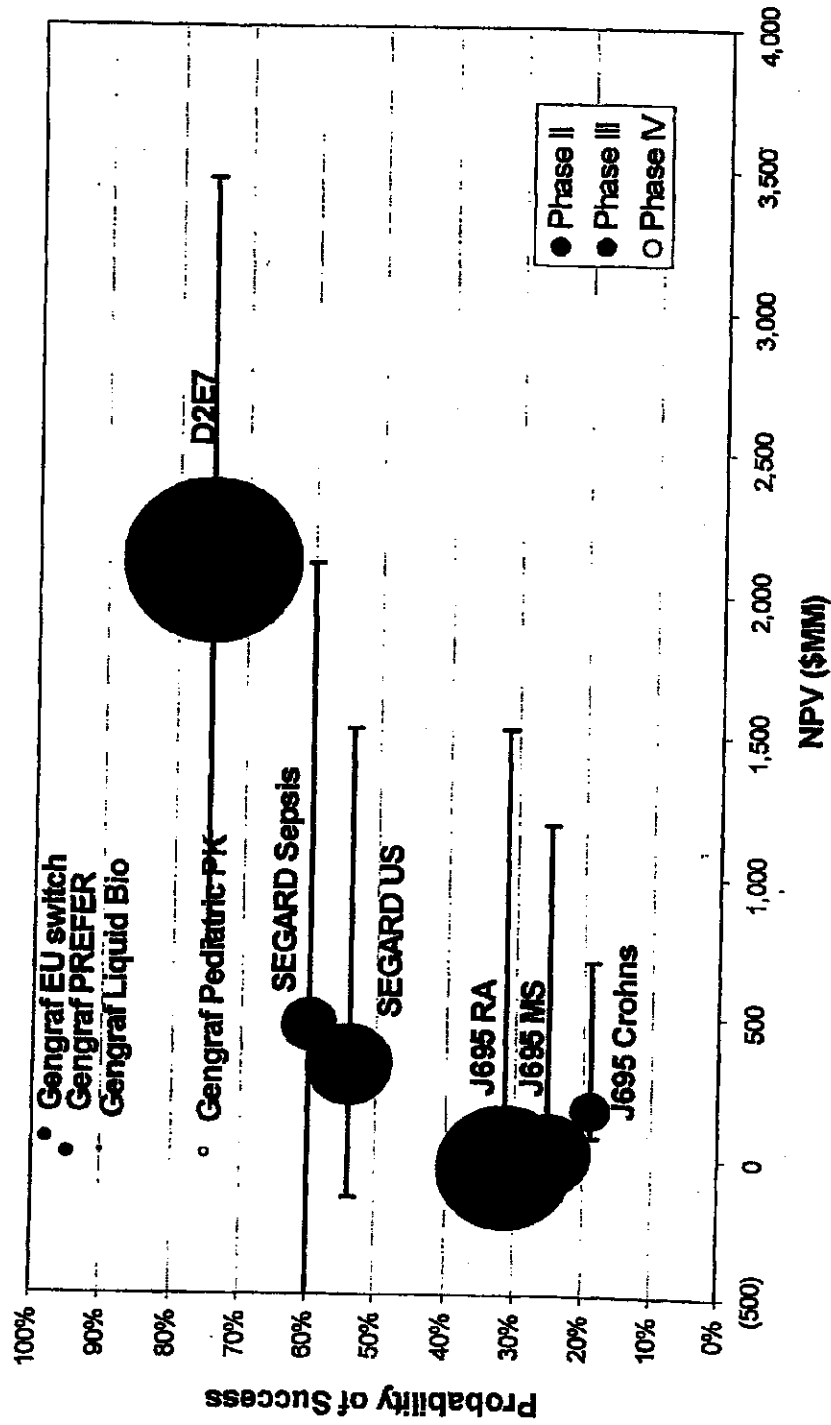
78

Gastro-intestinal



4/20/01

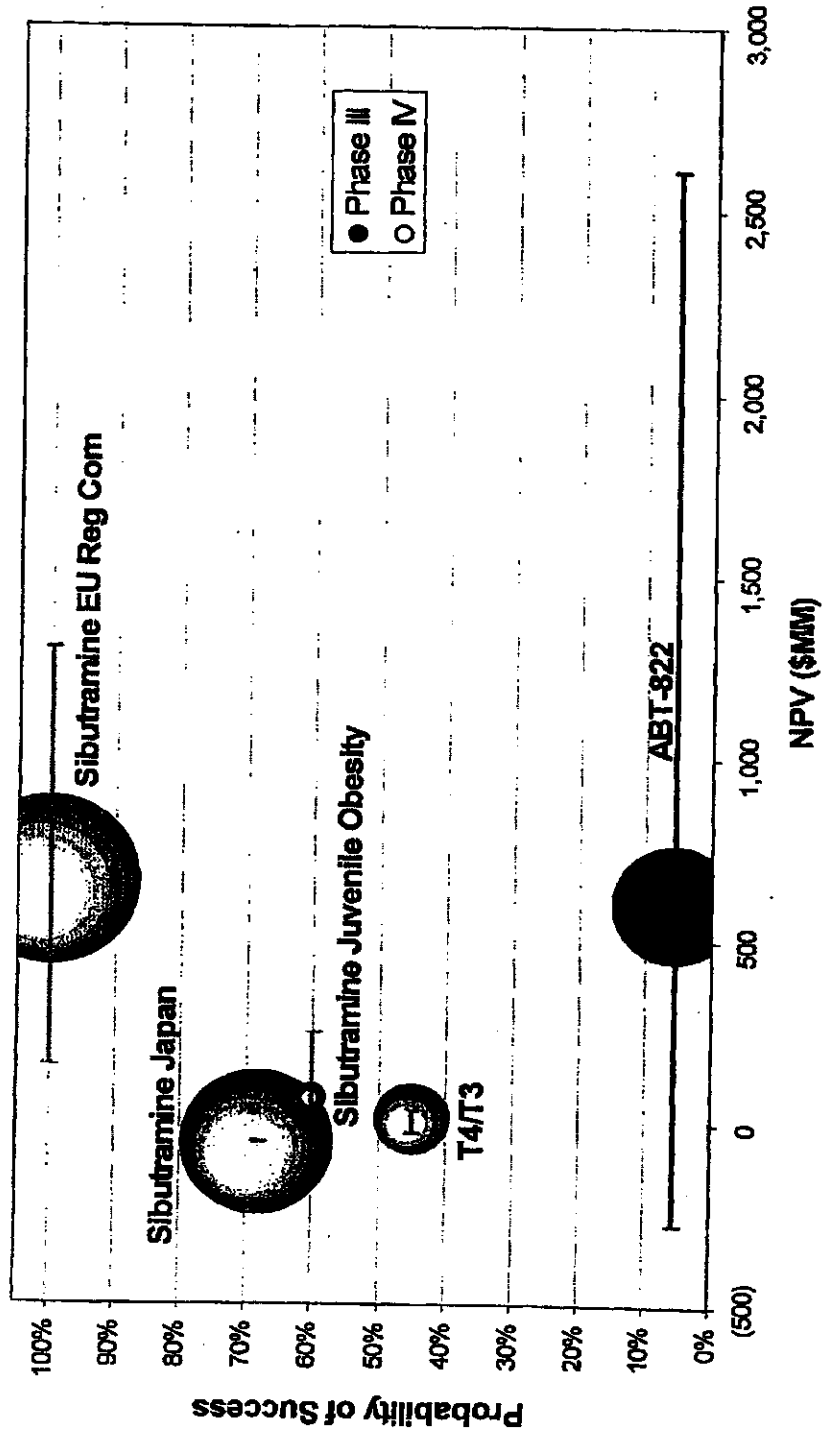
Inflammatory Diseases



4/20/01

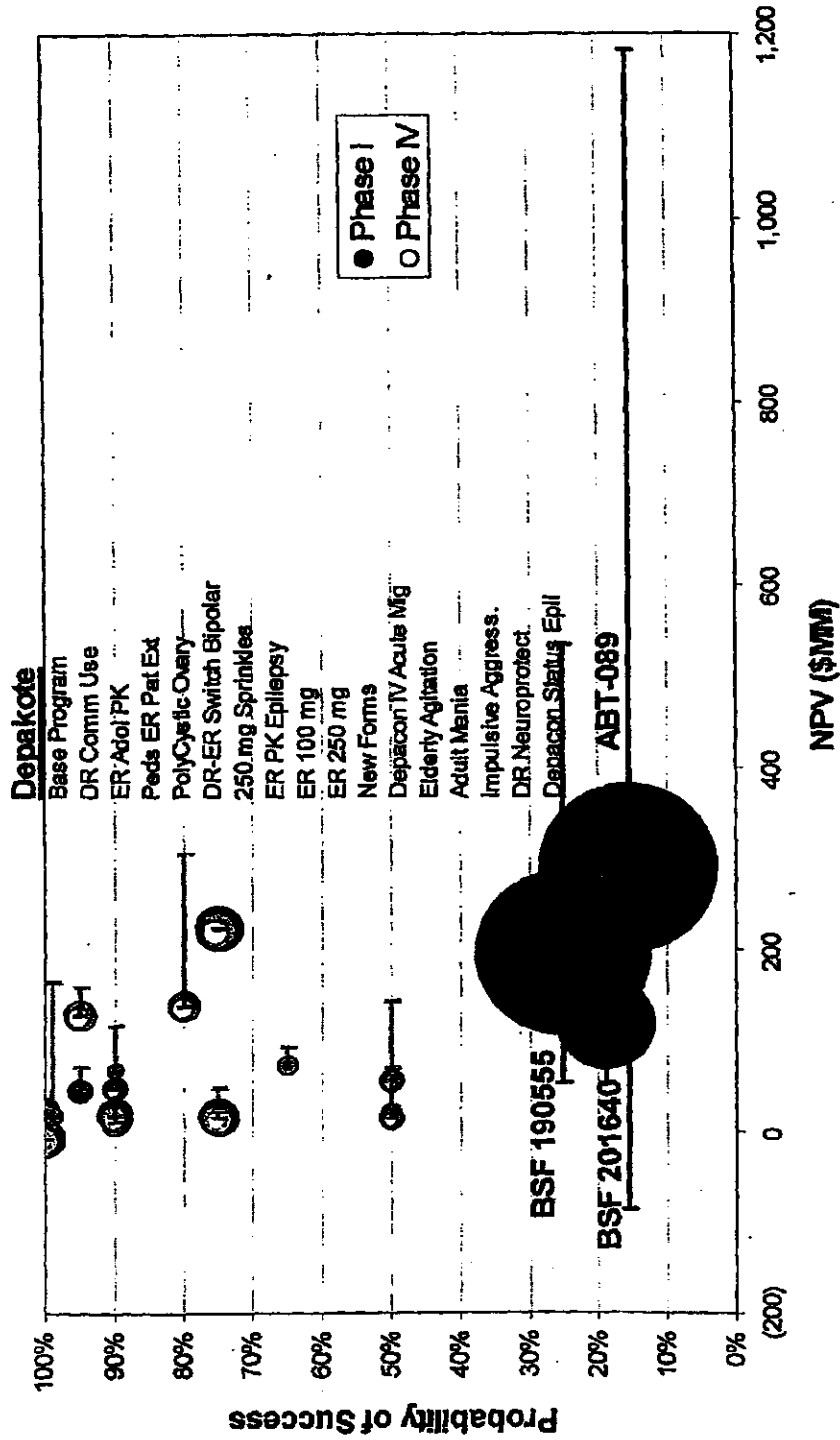
80

Metabolic Diseases



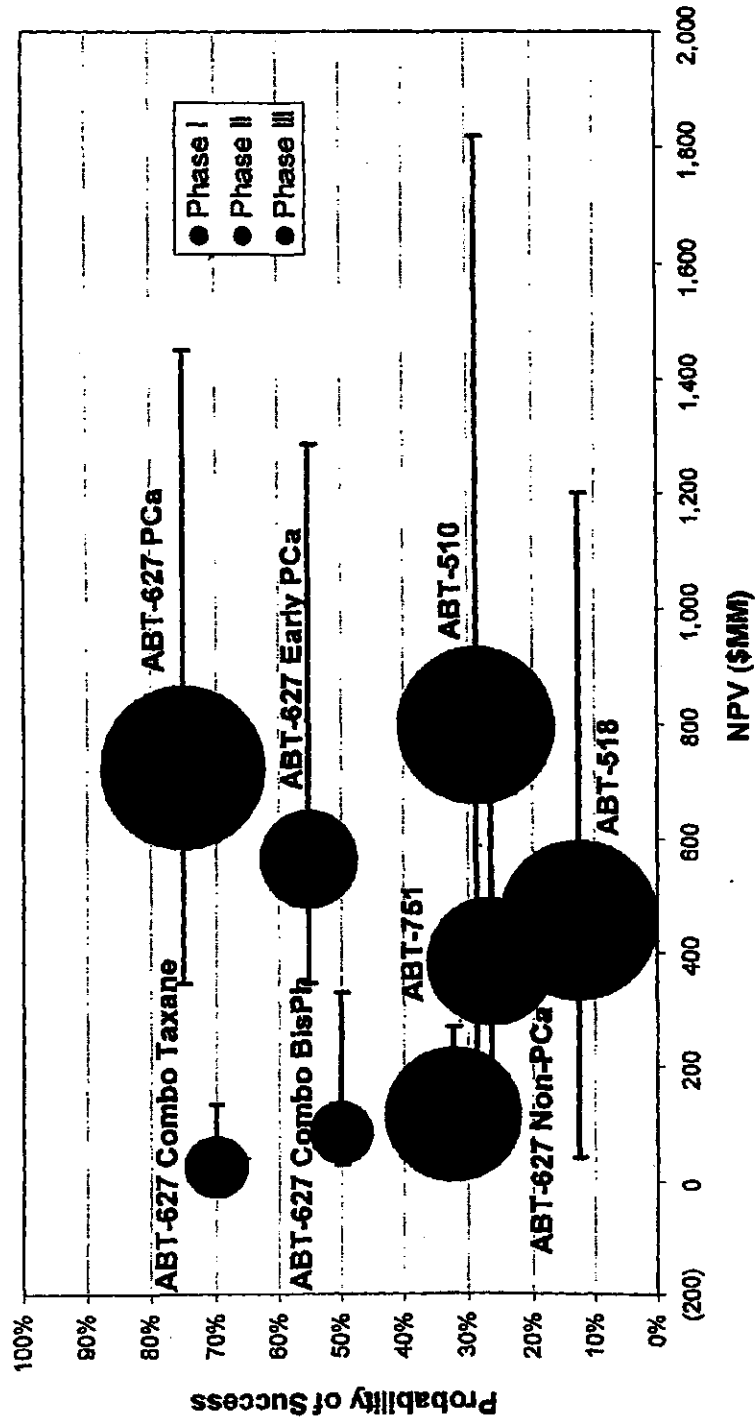
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Neurological Diseases



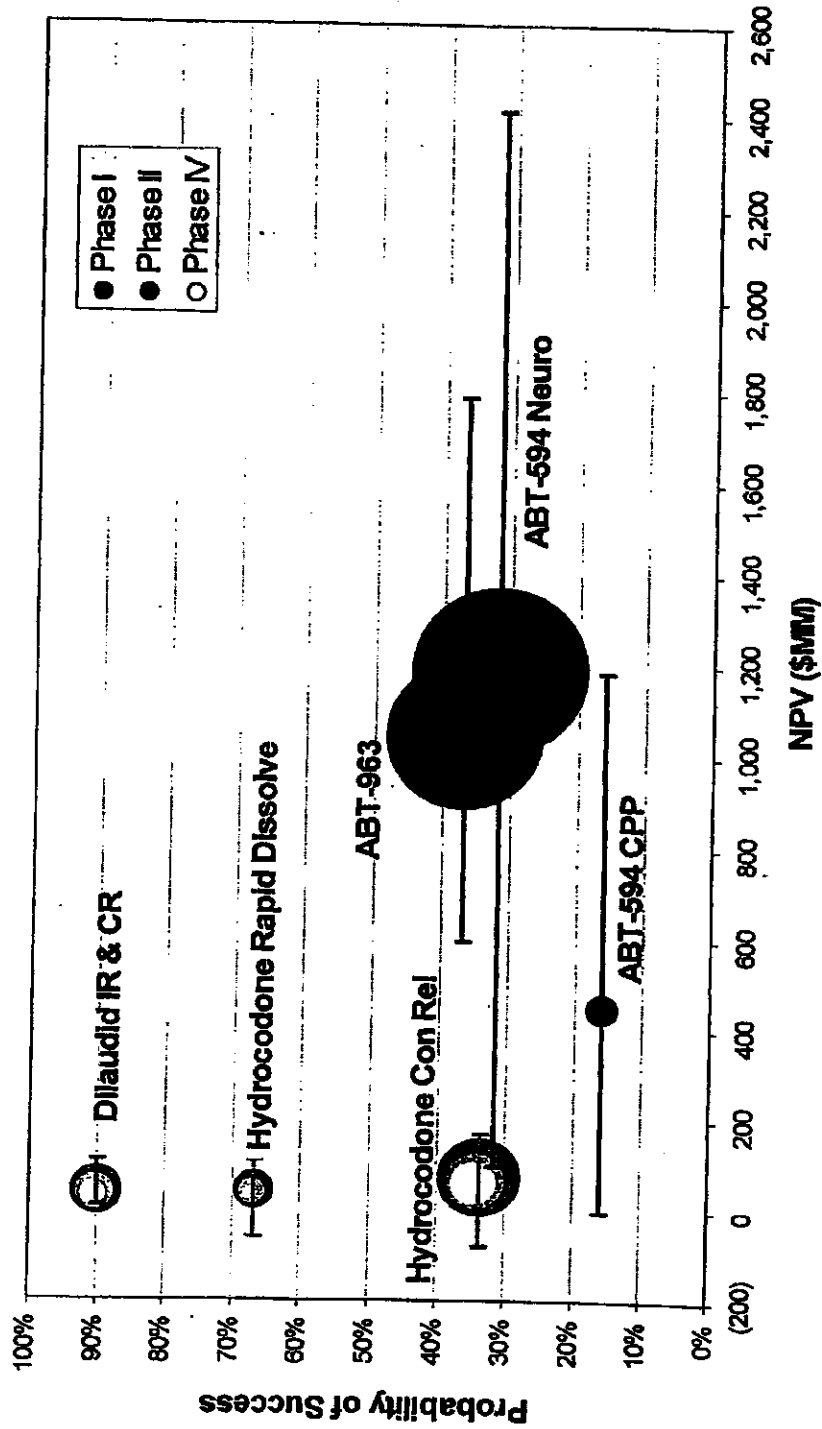
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Oncology



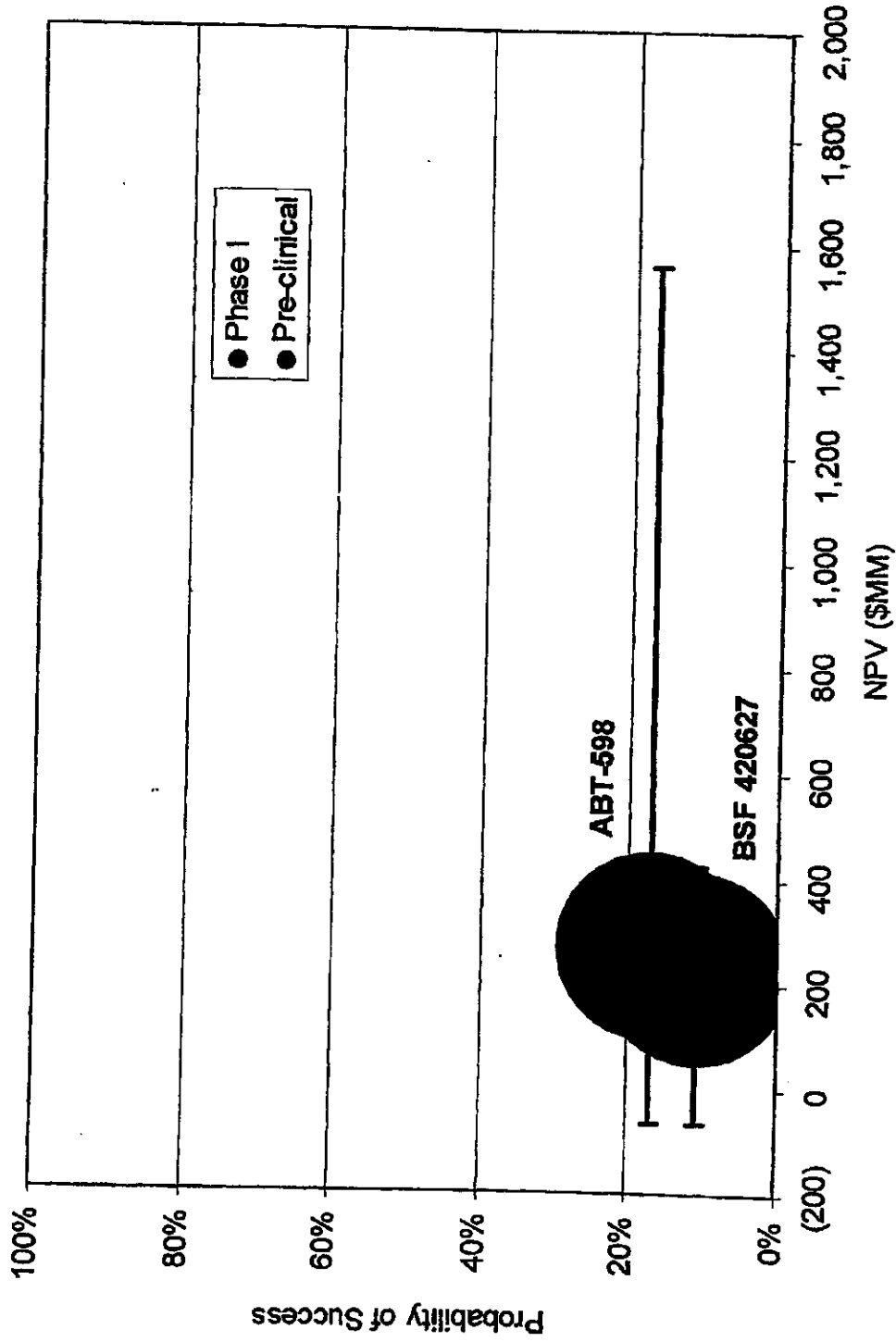
4/20/01

Pain



4/20/01

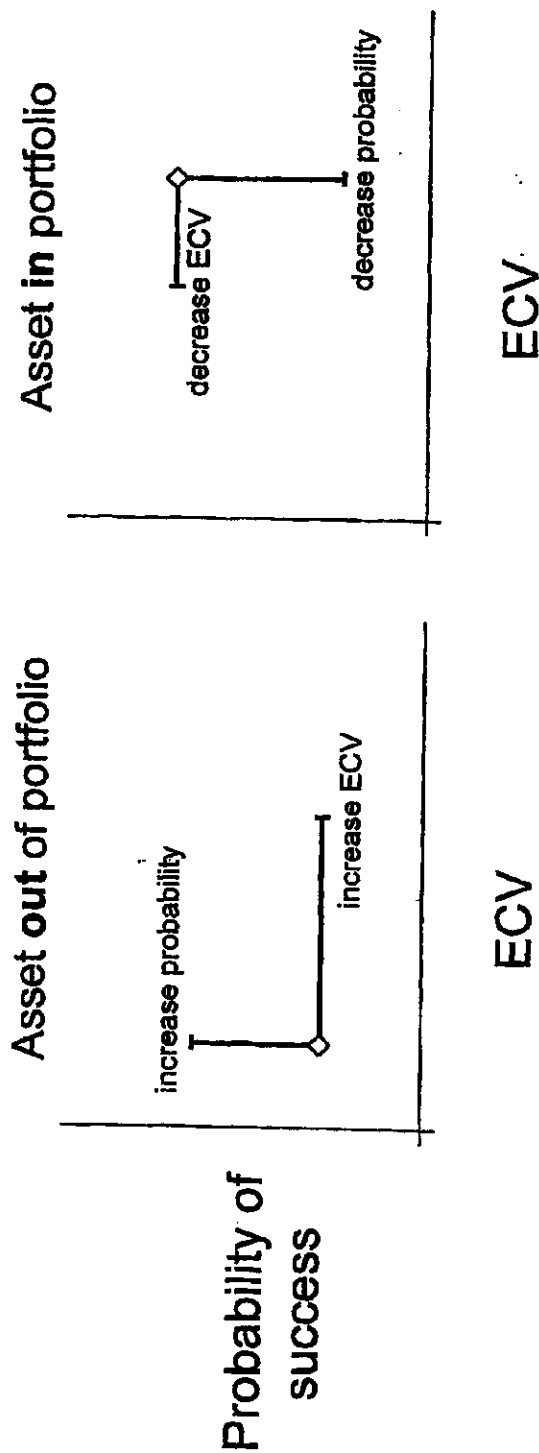
Urology



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Sensitivity of portfolio projects to probability and commercial assessments

- The expected value and probability of success for all assets are displayed by phase.
- Error bars indicate the change in the assessments of probability or expected commercial value (ECV) to the funding cut off for the Phase III Biased, 20% Phase IV portfolio.



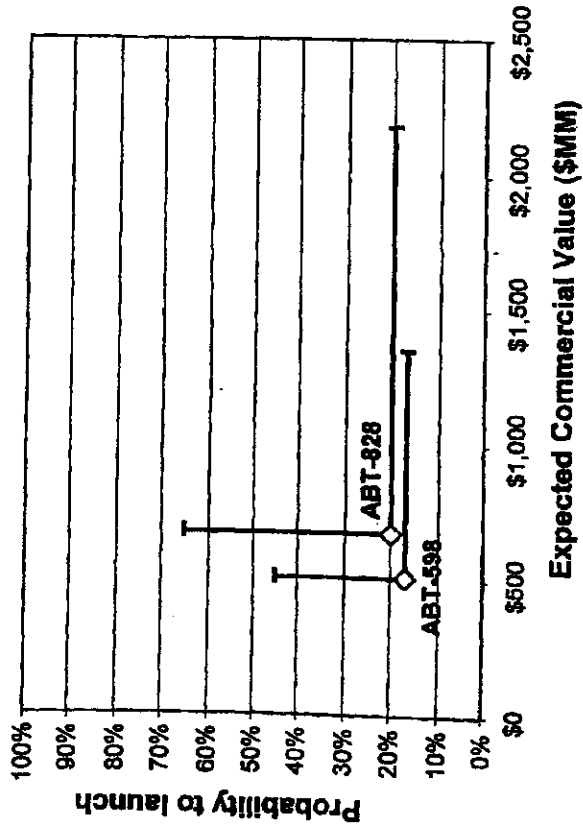
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86

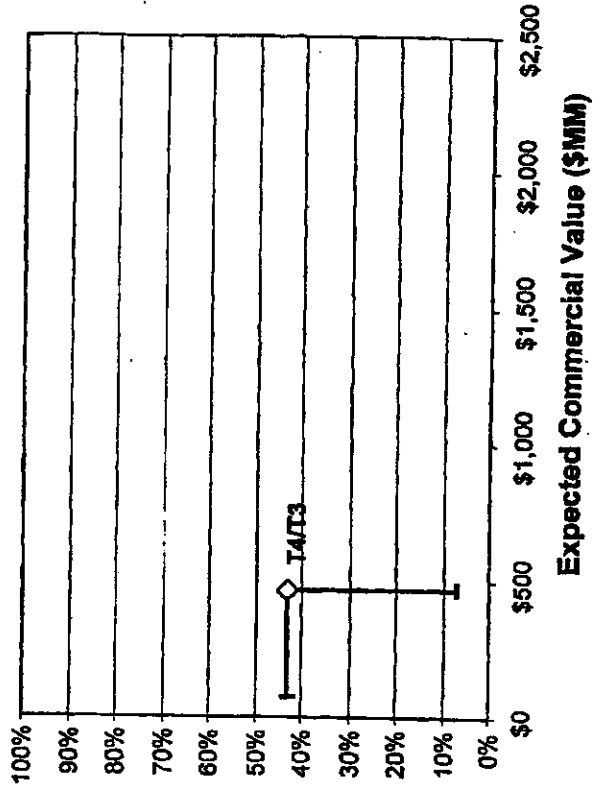
Preclinical Projects

\$500MM
Phase III Bias
20% Phase IV

Projects out of portfolio



Projects in portfolio



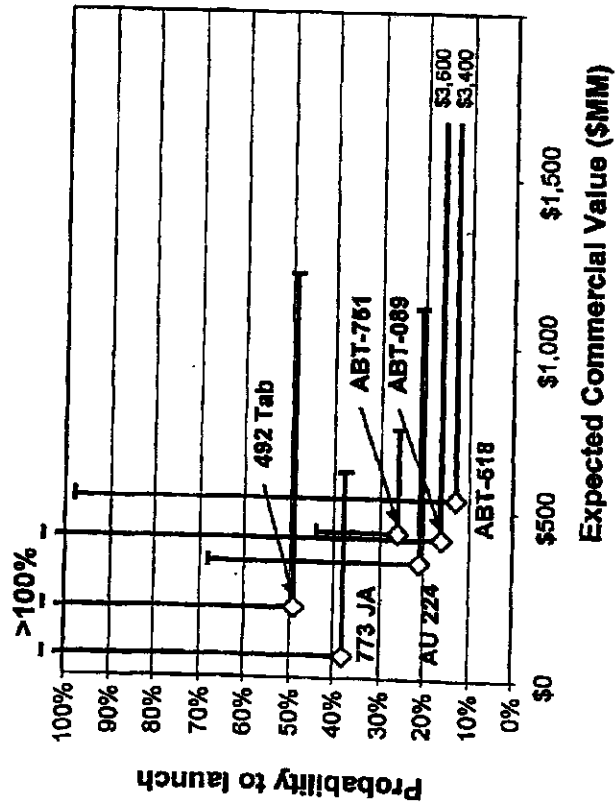
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87

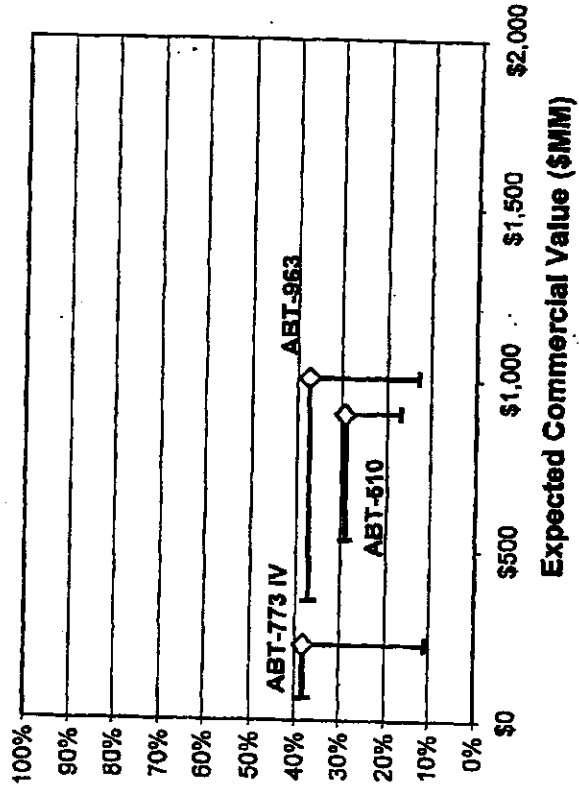
Phase I projects

\$500MM
Phase III Bias
20% Phase IV

Projects out of portfolio



Projects in portfolio



4/20/01

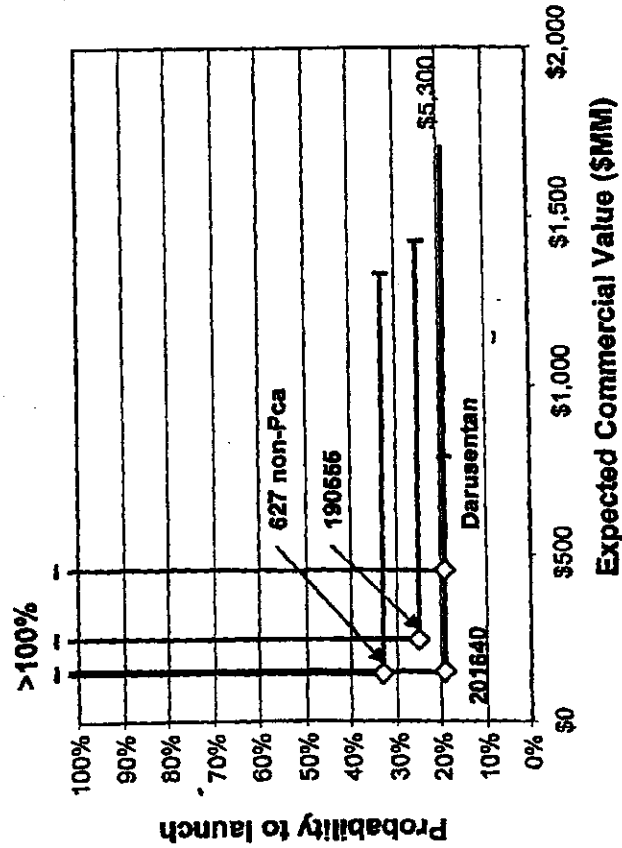
88

Phase II projects

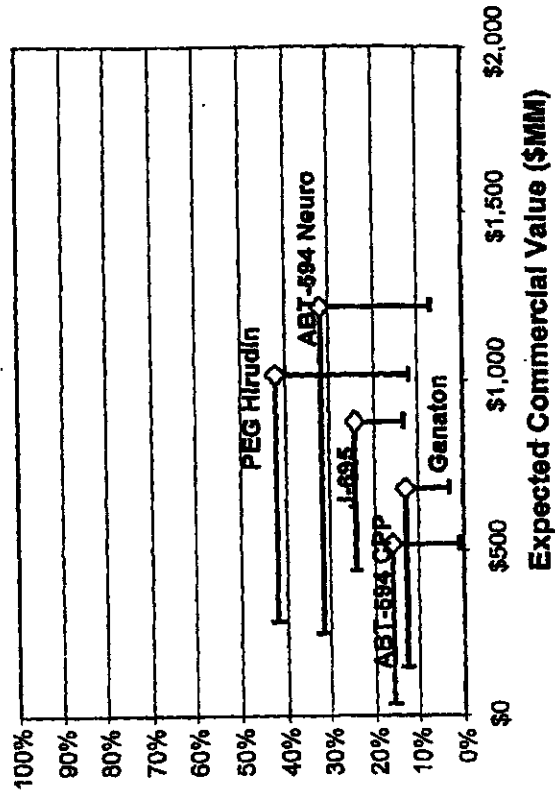
\$500MM

Phase III Bias
20% Phase IV

Projects out of portfolio



Projects in portfolio



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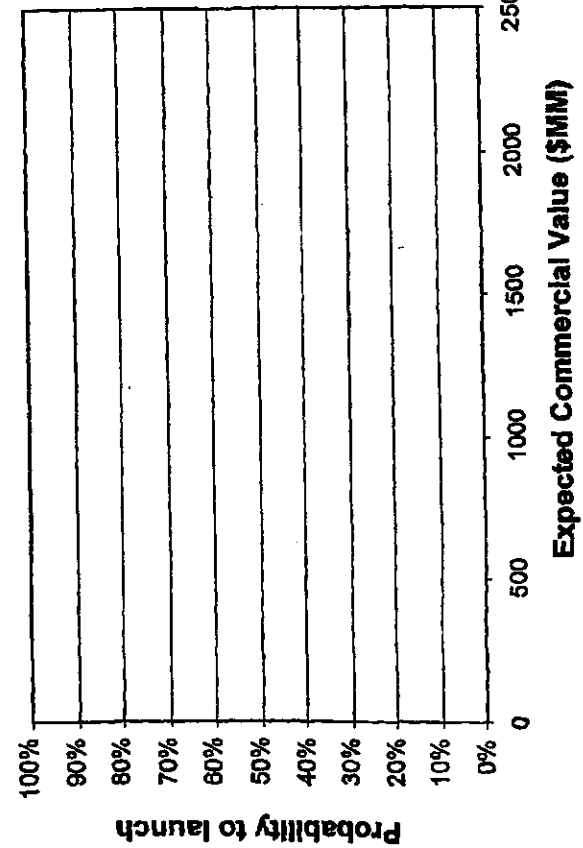
89

\$500MM

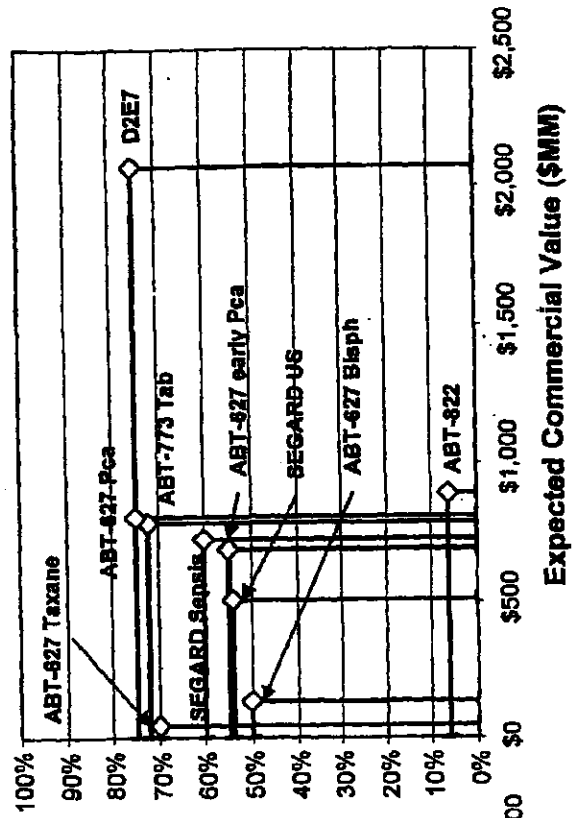
**Phase III Bias
20% Phase IV**

Phase III projects

Projects out of portfolio



Projects in portfolio



4/20/01

90

91

Extras

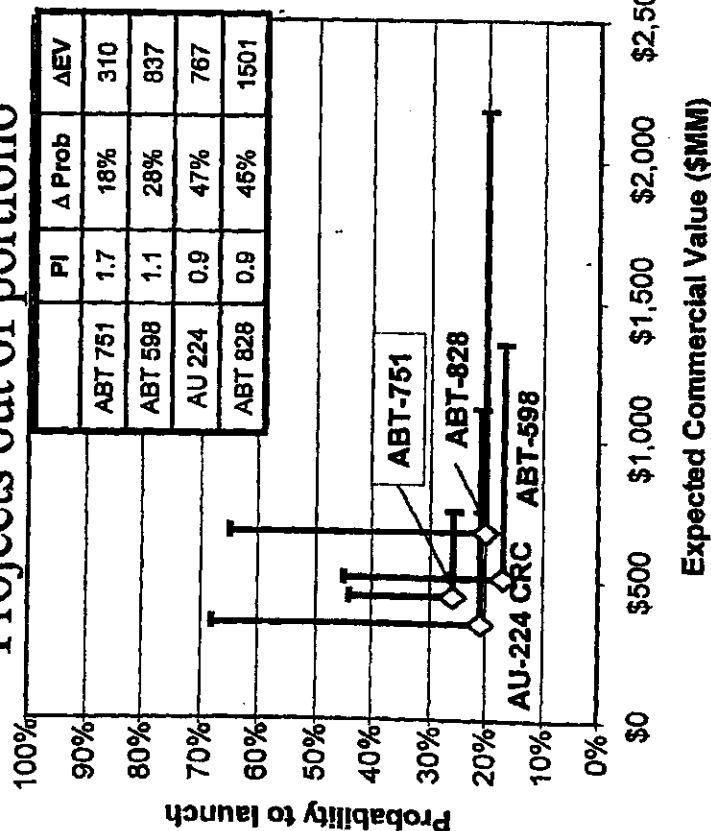
4/20/01

Highly Confidential

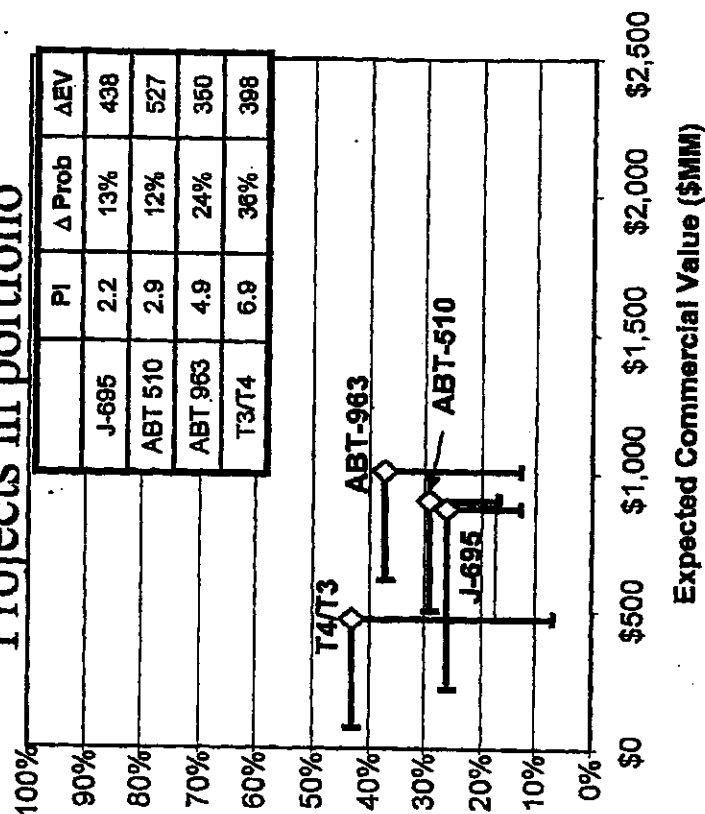
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A sensitivity analysis displays the required change in the assessed probability of launch or EV for the assets closest to the funding line.

Projects out of portfolio



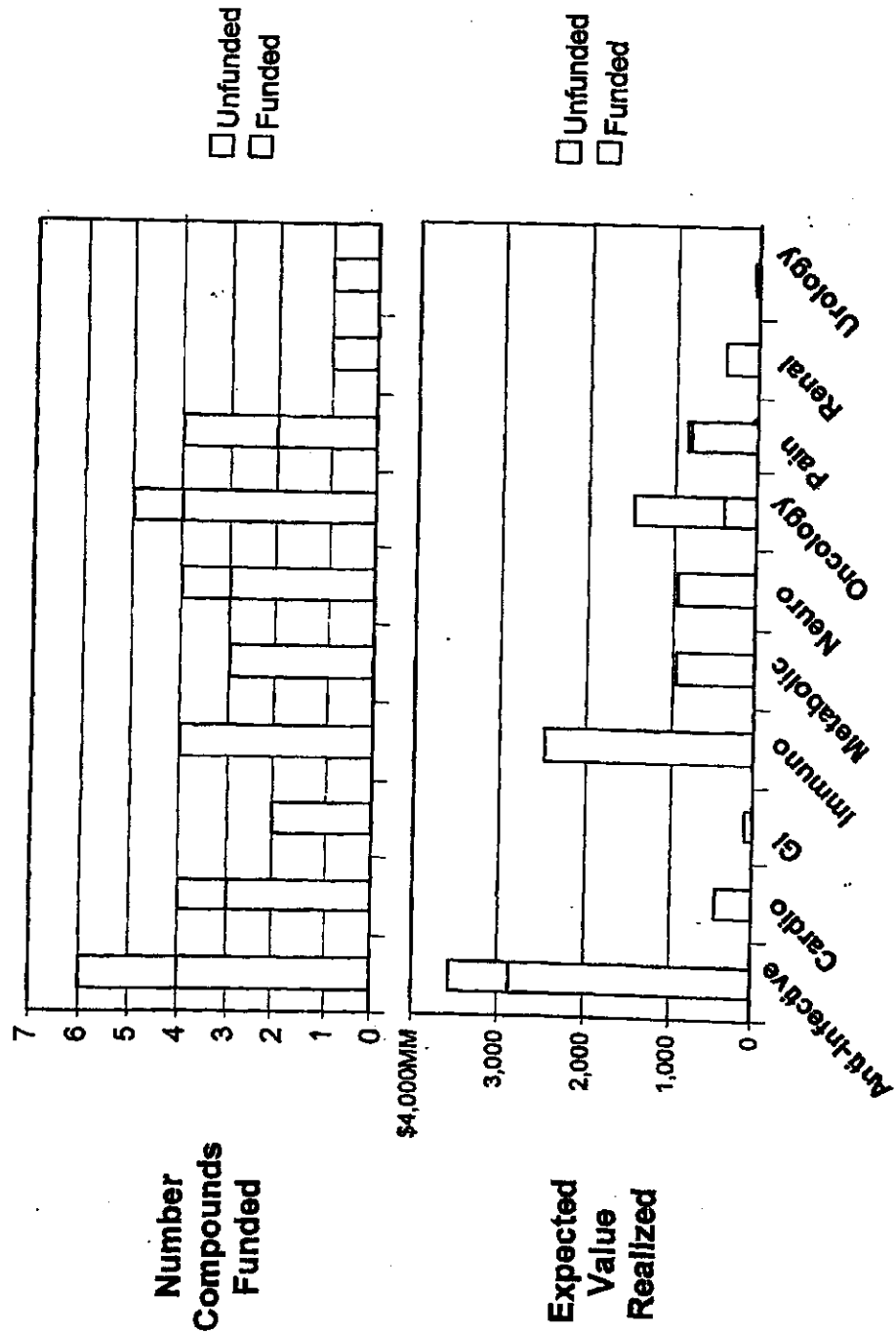
Projects in portfolio



4/20/01

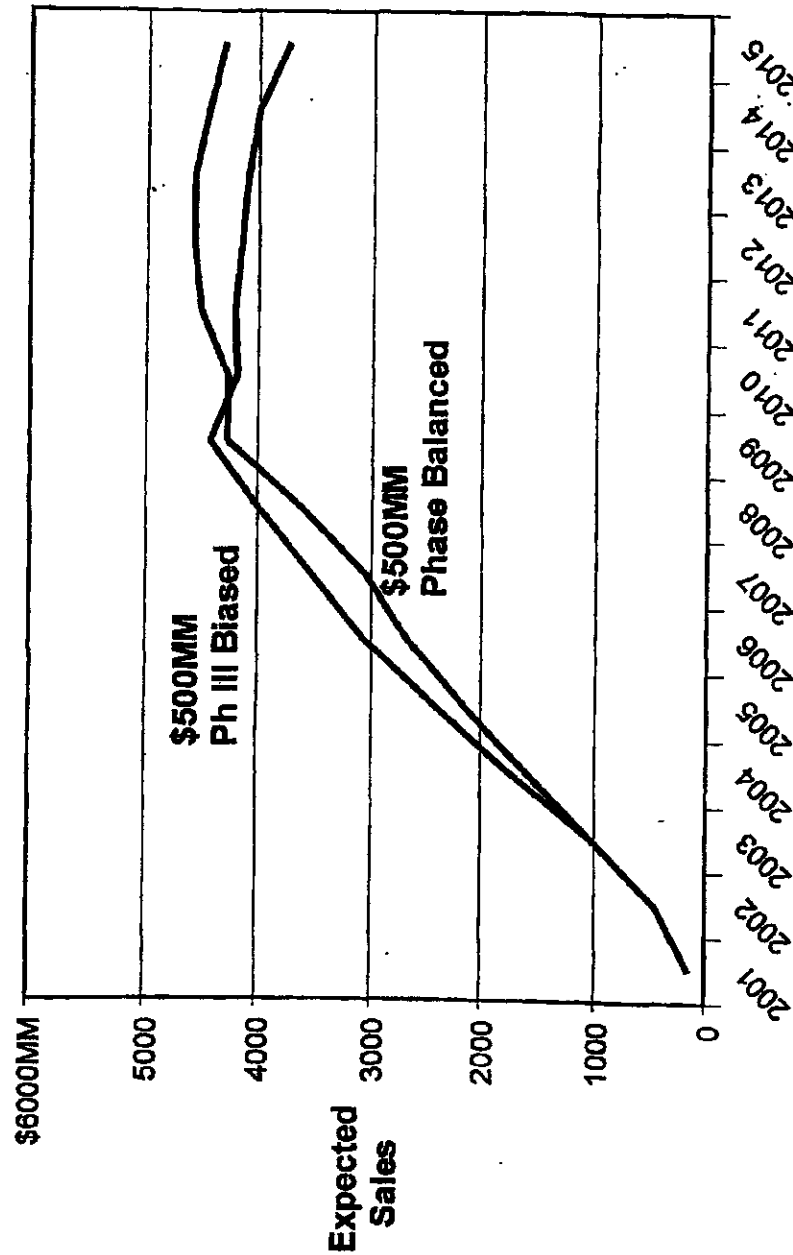
92

The \$500MM phase balanced portfolio favors therapeutic areas with less mature asset mix.



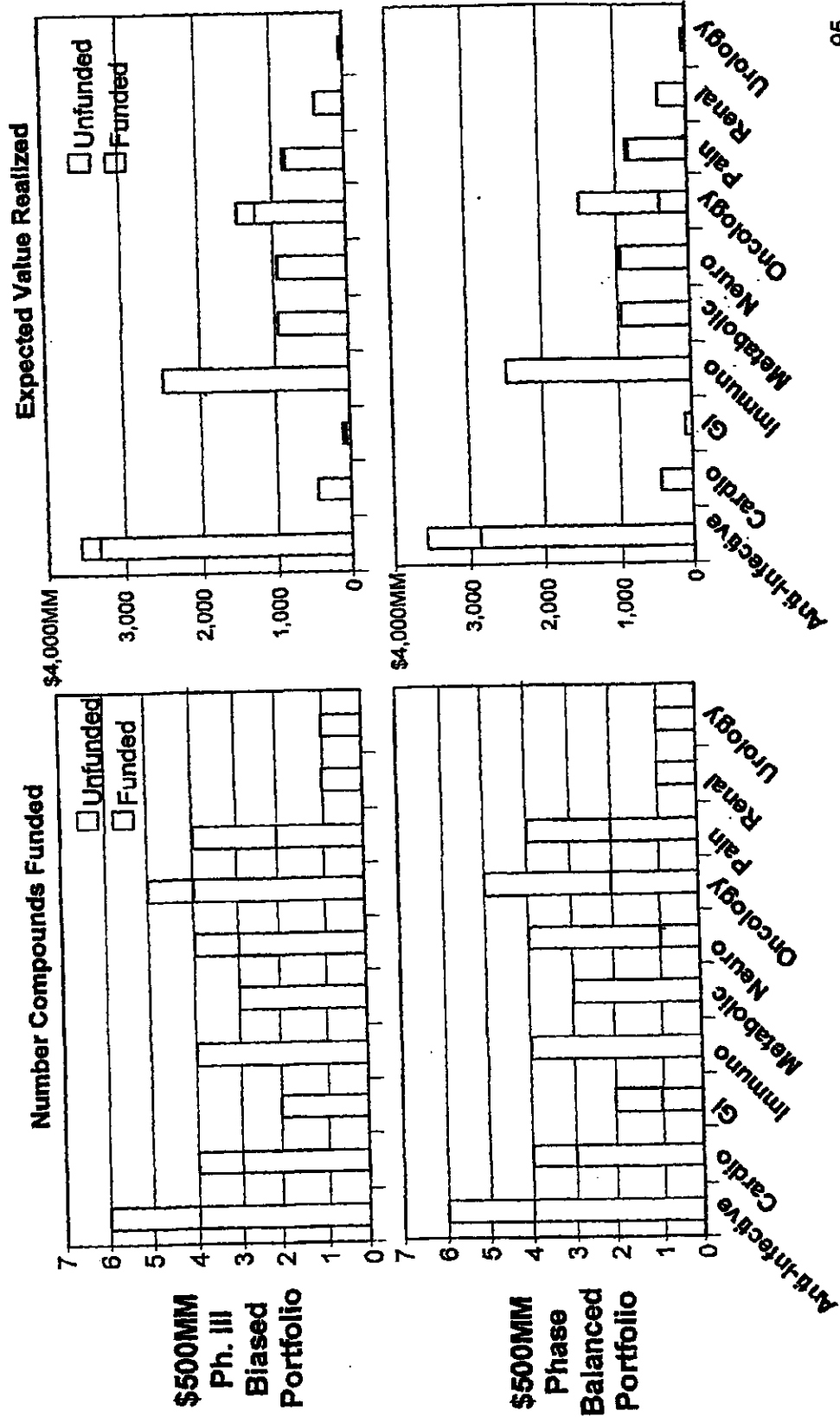
4/20/01

The Ph. III biased portfolio generates greater medium-term revenues at the expense of long-term revenues.



4/20/01

The Ph. III biased portfolio favors therapeutic areas with a more mature asset mix.



4/20/01

Leonard Deposition Exhibit 35

P's Exhibit MR

John M
Leonard/LAKE/PPRD/ABBO
TT

06/27/2001 03:31 PM

To Vaseem Iftikhar/PARSIPPANY/GPRD/ABBOTT@ABBOTT,
Matthias Luz/KNOLL-AG/BASF@KNOLL-AG, Clive E
Spiegler/PARSIPPANY/GPRD/ABBOTT@ABBOTT, Bob
Barrett/KNOLL-UK/BASF@KNOLL-UK, Perry D
Nisen/LAKE/PPRD/ABBOTT@ABBOTT
Friedrich Richter/KNOLL-AG/BASF@KNOLL-AG, Richard G
Granneman/LAKE/PPRD/ABBOTT@ABBOTT, Reid
Patterson/LAKE/PPRD/ABBOTT@ABBOTT, Efraim
Shek/LAKE/PPRD/ABBOTT@ABBOTT, Eugene X
Sun/LAKE/PPRD/ABBOTT@ABBOTT, Marleen H
Verlinden/LAKE/PPRD/ABBOTT@ABBOTT, David J
Pizzuti/LAKE/PPRD/ABBOTT@ABBOTT, Steffen
Roellinger/KNOLL-AG/BASF@KNOLL-AG, Iris
Loew-Friedrich/KNOLL-AG/BASF@KNOLL-AG, Olaf
cc Lischke/KNOLL-AG/BASF@KNOLL-AG, Jerry L
Osborne/PARSIPPANY/GPRD/ABBOTT@ABBOTT, Mike
Rubison/LAKE/PPRD/ABBOTT@ABBOTT, Winfried
Koch/KNOLL-AG/BASF@KNOLL-AG, Jeffrey L
Meeks/PARSIPPANY/GPRD/ABBOTT@ABBOTT, Thomas
J Lyons/LAKE/PPRD/ABBOTT@ABBOTT, Thomas E
Woidat/LAKE/PPRD/ABBOTT@ABBOTT, Kenneth D
Stiles/LAKE/PPRD/ABBOTT@ABBOTT, David J
Pizzuti/LAKE/PPRD/ABBOTT@ABBOTT, Gillian
Hodkinson/LAKE/PPRD/ABBOTT@ABBOTT

bcc

Subject Terminated Development Projects

As each of you are aware, as part of the Abbott Pharmaceuticals development portfolio rationalization, the decision has been made to terminate several development projects effective immediately. It is critical therefore that Project Management take the appropriate immediate actions necessary to execute the project terminations in a timely and organized manner such that related 2001 spending savings can be maximized. This correspondence is intended to communicate the projects that have been deemed terminated by management, and outline expectations in terms of targeted 2001 savings and milestone tracking during the shut-down process.

1) Terminated Development Projects

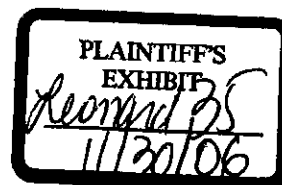
Please refer to the file attachment "Project Terminations". This matrix depicts names of terminated projects, names of primary responsibility contacts, targeted 2001 external savings, revised 2001 external spending targets and comments / key next steps.

In addition to the terminated projects, there are other projects with pending status that may or may not result in termination decisions or related 2001 savings. However, the focus of this communication is the projects for which a termination decision has already been made.

Site-specific adjustments to spending targets have not been identified in the attached. You will need to coordinate / communicate adjustments on a site basis to ensure the total project spending reductions are achieved. The site specific adjustments will enable closure on final April Update spending targets. Work closely with your Finance support groups on this.

2) Milestone Reporting - Terminated Projects

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ABBT334140

Similar to the milestone tracking that will occur for the Knoll Integration Synergy Initiatives, it is critical that key milestones be defined and tracked for each of the individual projects that have been terminated. It is necessary not only to identify and document the key milestones and actions that need to take place in order to effectively execute the project shut-downs, but also to monitor progress toward achieving the milestones and the related project savings. To this end, we are requesting that each contact complete the attached template (SI-4) with key milestones, responsibility contacts, and planned completion dates for each project. Please complete the file, rename it (SI-4_PROJECT NAME", e.g. SI-4_T3T4), and E-mail it to the attention of Thomas Woidat no later than Friday June 29). Beginning in July, GPRD will begin a reporting process to track progress on the synergy initiatives and project termination milestones. Additional instructions regarding this process will be forthcoming.



Project Terminations.xls: SI-4.xls

John Leonard

**ABBOTT PHARMACEUTICAL RESEARCH & DEVELOPMENT
TERMINATED DEVELOPMENT PROJECTS**

PROJECT NAME	PRIMARY RESPONSIBILITY CONTACT	FULL YEAR 2001 EXTERNAL BUDGET (U.S. \$MM)			MEMO: 2001 3Q2001 CLOSE REVISED TARGET	COMMENTS / KEY NEXT STEPS
		ORIGINAL FORECAST	SAVINGS	REVISED TARGET		
Pag Marin	Vaseem Rukhar	13.4	(7.3)	6.1	4.5	- Stop patient recruitment and maximize spending savings
LU 135252 (Dorasetan)	Matthias Luz	13.8	(6.9)	6.9	4.9	- Single CHF study underway (until year-end only) - Hypertension program stopped - Decision is to spin off franchise or shutdown
BSF-302146 (Dorasetan Backup)	Matthias Luz	0.3	(0.3)	-	-	- Program terminated due to excessive testicular findings in rats
OzE7 Other (U.S.)	Clive Spiegler	2.7	(2.7)	-	-	- Phase IIB no program description available
Dilaudid	Bob Barrett	2.2	(1.7)	0.5	0.5	- Various U.S. Phase IV studies
Vicoprofen	Jeff Drajesh	1.2	(0.8)	0.4	0.3	- Various U.S. Phase IV studies
T3/T4	Vaseem Rukhar	4.8	(3.5)	1.3	0.9	- Program requires FDA review but local counsel has advised no activity with FDA due to Synthroid. Single clinical study continues with no new activity
BSF-420627	Matthias Luz	0.7	(0.2)	0.5	0.4	- BPH - Team recommends not to proceed based upon competitive intelligence and concern for mechanism of action
ABT-518	Perry Nisen	1.1	(0.8)	0.3	0.3	- Stop enrollment of new patients in Phase I Multiple Dose Study (MCO-235)

MEMO: TOTAL TARGETED SAVINGS, TERMINATED PROJECTS (24.3)

(1) AMOUNTS REPRESENT 2001 TARGETED EXTERNAL SAVINGS BASED ON JUNE 2001 SHUTDOWN; EFFORTS SHOULD BE MADE TO ACHIEVE OR SURPASS THESE SAVINGS TARGETS; ABOVE DATA PRESENTED IN MILLIONS OF U.S. DOLLARS (U.S. \$ = 98 EURO)

pmw

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ABBT334142

[DATE]

[TIME]

INITIATIVES (Template)**MILESTONES**

Initiative - Terminate Development Project

Project Name - INPUT

	Milestone (1)	Example:	Responsibility	Planned completion	Revised completion	Status*	
						G	Y
1)	MH-049 - Notify CRO/investigators of termination plan		John Doe	7/31/2001			
2)	Clinical completion (last patient visit)		John Doe	8/31/2001			
3)	Abbreviate (GCP) report available		John Doe	12/31/2001			
4)							
5)							
6)							
7)							
8)							
9)							
10)							
11)							
12)							
13)							
14)							
15)							

* Enter an "X" in each of the three columns when milestone is reached successfully

** Must be completed if yellow or red

(1) Please define key milestones/actions for individual sites so that progress toward these milestones can be tracked

Green = Milestone is likely to be achieved on its planned completion date or its revised completion date

Yellow = Milestone may not be achieved on time because of developing issues

Red = Milestone is in serious jeopardy of not being achieved on time if issues are not resolved

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ABBT334143

[DATE]

[TIME]

|

Highly Confidential

ABBT334144

[DATE]

[TIME]

SI-4)

[illegible]

notes
f

Highly Confidential

ABBT334145

Leonard Deposition Exhibit 38

P's Exhibit FY

Elizabeth Kowaluk/LAKE/PPRD/ABBOTT
07/30/2001 02:23 PM
To: Steve C Kuemmerle/LAKE/PPRD/ABBOTT@ABBOTT
cc
bcc
Subject: ABT-594 DSG analysis - preview meetings

Steve

I guess I did cc you on my e-mail to Keith - I trust you got it

Liz

----- Forwarded by Elizabeth Kowaluk/LAKE/PPRD/ABBOTT on 07/30/01 02:22 PM -----

Elizabeth Kowaluk
07/30/01 12:49 PM
To: Keith F Hendricks/LAKE/AI/ABBOTT@ABBOTT
cc: Steve C Kuemmerle/LAKE/PPRD/ABBOTT@ABBOTT
Subject: ABT-594 DSG analysis - preview meetings

Keith,

We are in the process of setting up meetings with key individuals to preview the ABT-594 DSG analysis (and probably related clinical and preclinical data) before the PEC presentation, which is currently scheduled for 8/21/01.

Steve and I have discussed the following series of meetings (hopefully in this order if we can get the schedules lined up):

Meeting #1:

Goal is to review with Marleen Verlinden (she has been to some, but not all of the team meetings)
Attendees: Marleen, Bruce McCarthy, Jim Sullivan, Mike Meyer, Rose Waleska, Danhui Wang, Steve K, yourself and me.

Meeting #2:

Goal is to review with Paul Berns (has requested an update on ABT-594 via Rose)
Attendees: Paul Berns, Chrys Kokino and all of the people in meeting #1

Meeting #3:

Goal is to review with key PEC members
Attendees: Dave Goffredo, Bill Dempsey, John Leonard, Dan Norbeck (Note: NNR Follow-on is also part of the analysis), and all of the people invited to meeting #2.

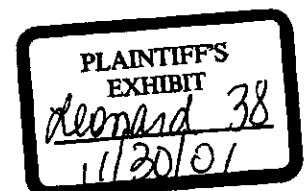
Is there anyone else we need to review this with - either by scheduling a separate meeting, or by including in one of the above meetings? Who would be the AI counterpart to Paul Berns? Do we need to include that person (or perhaps John Arnot) in the Berns Meeting?

Thanks in advance for your input

Liz

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ABBT317214



Leonard Deposition Exhibit 45

P's Exhibit 28

John M
Leonard/LAKE/PPRD/ABBO
TT
12/14/2001 04:05 PM
To: Stan Bukofzer/LAKE/PPRD/ABBOTT
cc
bcc
Subject: Re: Dec. 12 PEMC Meeting Minutes

John M. Leonard, M.D.
Vice President
Global Pharmaceutical Drug Development
Global Pharmaceutical Research and Development
PH: (847) 938-4545
FX: (847) 937-3918
Vickie Enders, Admin. (847-935-1905)
----- Forwarded by John M. Leonard/LAKE/PPRD/ABBOTT on 12/14/2001 04:05 PM -----

John M Leonard
12/14/2001 03:41 PM
To: Eugene X Sun/LAKE/PPRD/ABBOTT
cc:
Subject: Re: Dec. 12 PEMC Meeting Minutes

Bryan wrote this after the meeting with input from Leiden and me . We will need to have an MDW summary presentation, but it should have said "if possible before the end of the year ." There was general agreement the sooner the better, but the likelihood of getting the meeting borders on zero . Plan for January and I will follow up next week with what is possible .

I also pointed out in the Exec Session that we did at least 75% of the presentation (interesting that the estimates are similar) which should make the MDW summary fairly straightforward . I don't think Leiden views it any differently .

Margo is not on the PEC; I'm sure that Bryan is just confused .

J
John M. Leonard, M.D.
Vice President
Global Pharmaceutical Drug Development
Global Pharmaceutical Research and Development
PH: (847) 938-4545
FX: (847) 937-3918
Vickie Enders, Admin. (847-935-1905)
Eugene X Sun

Eugene X Sun
12/13/2001 05:49 AM
To: john leonard
cc:
Subject: Re: Dec. 12 PEMC Meeting Minutes

John,
The Miles presentation is news to me as well. Did this come out of the exec session or later? I also notice, as did Stan, that the presentations were attributed to "Jerry Wenker's and John Arnott's teams." As I recall, about 80% of the presentation time was by Stan, Scott, and Shing, who are also the ones who spent the most time thinking about it and putting it together. I can think of at least 10 other people who expended more neurotransmitters than Jerry and John. Perhaps this is petty, or just reflects Bryan's ignorance, but if it represents Jeff's or a more general perception, it is disturbing. Is Margo now on the PEC, as the memo seems to imply? If it's not a bad joke or another gaffe by Bryan, the PEC loses credibility for me and, I would guess, a substantial portion of the R&D organization.

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ABBT209485

Stan Bukofzer



Stan Bukofzer
12/12/01 07:23 PM

To: Eugene X Sun/LAKE/PPRD/ABBOTT@ABBOTT
cc: John M Leonard/LAKE/PPRD/ABBOTT@ABBOTT
Subject: Re: Dec. 12 PEMC Meeting Minutes [3]

E

I note that a slide presentation of the 773 issues is to be prepared for Miles in Dec. Any idea when is that planned for as I had planned a holiday in dec22nd onwards. I really need it and with ICCAAC

Stan

Bryan A Ford



Bryan A Ford
12/12/01 05:11 PM

To: Michael G Beatrice/LAKE/CORP/ABBOTT@ABBOTT, Christopher Begley/HPD/Abbott@Exchange, William G Dempsey/LAKE/AI/ABBOTT@ABBOTT, David B Gotfred/LAKE/PPD/ABBOTT@ABBOTT, Richard A Gonzalez/LAKE/CORP/ABBOTT@ABBOTT, Robert I Kamen/WORCESTER/GPRD/ABBOTT@ABBOTT, John M Leonard/LAKE/PPRD/ABBOTT@ABBOTT, Dan W Norbeck/LAKE/PPRD/ABBOTT@ABBOTT, Ed Ogunro/HPD/Abbott@Exchange, James L Tyree/LAKE/GPRD/ABBOTT@ABBOTT, Steven J Weger/LAKE/CORP/ABBOTT@ABBOTT, Lance B Wyatt/LAKE/CAPD/ABBOTT@ABBOTT, Margo E Chiozz/LAKE/PPRD/ABBOTT@ABBOTT
cc: John Amott/LAKE/AI/ABBOTT@ABBOTT, Siobhan NiBhuachalla/LAKE/PPRD/ABBOTT@ABBOTT, Eugene X Sun/LAKE/PPRD/ABBOTT@ABBOTT, Jerald J Wenker/LAKE/PPD/ABBOTT@ABBOTT, Stan Bukofzer/LAKE/PPRD/ABBOTT@ABBOTT
Subject: Dec. 12 PEMC Meeting Minutes

Attached are the meeting minutes from Monday's PEMC. The meeting minutes are highly confidential and should not be shared with others at this time



pemc.dec10.mtg.doc

Bryan A. Ford
Director Strategic Scientific Operations
Bldg. AP9-1, GPRD
847-935-6368

Highly Confidential

ABBT209486

Leonard Deposition Exhibit 48

P's Exhibit NH



Gayle A
Kirkpatrick /LAKE/GPRD/AB
BOTT
09/23/2002 11:20 PM

To: Suzanne Lebold/LAKE/PPRD/ABBOTT@ABBOTT
Ake L Johansson/LAKE/GPRD/ABBOTT@ABBOTT,
cc: Thomas J Lyons/LAKE/PPRD/ABBOTT@ABBOTT, William
L Mathers/LAKE/GPRD/ABBOTT@ABBOTT
bcc:
Subject: Re: Status of JH compounds/Divestment activities [2]

Suzy,

In response to your email of 9/18 and information needed for an October review w/JH, I've polled the SA team and comments are as follows:

ABT-100: no outlicensing activities have been initiated per JHV.

ABT-518: See attached summary from John Fitz Gerald/JHV.

ABT-594: per Kevin and Jim Sullivan, this is not in current development and has NOT been publically communicated. ABT has focused on ABT-202, the back-up cmpd that has a more favorable pdt profile that ABT-594.

ABT-773: SM has assisted Ake with an outlicensing package.

Let me know if any additional information is needed from the SA team



ABT518 Outlicense History.doc

Gayle Kirkpatrick
Director, Scientific Assessment & Technology Licensing
Global Licensing and New Business Development
Abbott Laboratories
200 Abbott Park Rd., D50H, AP34-2
Abbott Park, IL 60064-6189

Tel: 847-938-3357
Fax: 847-937-1771
Email: gayle.kirkpatrick@abbott.com
Suzanne Lebold



Suzanne Lebold
09/13/2002 06:55 PM

To: Gayle A Kirkpatrick/LAKE/GPRD/ABBOTT@ABBOTT, Ake L
Johansson/LAKE/GPRD/ABBOTT@ABBOTT
cc: William L Mathers/LAKE/GPRD/ABBOTT@ABBOTT, Thomas J
Lyons/LAKE/PPRD/ABBOTT@ABBOTT
Subject: Status of JH compounds/Divestment activities

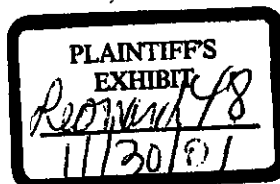
Gayle and Ake:

John Hancock has asked for a status update by 10/15 on the following compounds/outlicensing activities [per the contract, if we drop a compound, activities to realize the value of the asset]:

- ABT-100 [Gayle, I think that Jane is handling, can you please have her summarize planned activities]
- ABT-518 [Gayle, do we have a summary of who did evaluate 518- and conclude we have exhausted the supply? I have some emails- but I don't know that it is complete- lets consolidate, ok?]

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ABBT334838



- ABT-594 [Gayle- can you get an update from Kevin on this- still in 'development' or finally killed?, and do we have plans to outlisc?]
- ABT-773 [Ake- if we could update the process/where we are since the last update that you gave me, which Tom Lyons and I delivered (verbally) to JH on 8/30- thank you.]

Ake has a great summary for 773- timeline of events/who was contacted/status of each/next steps- which I think is appropriate for the others.

Please let me know if you have any questions or need any additional information

JH has a quarterly meeting with Tom Lyons and have asked us to provide this which we are contractually obligated to do. I have Michelle summarizing Article 4 of the agreement to show the rules of the road for each 'bucket' of compounds (and which compounds are treated in which manner), as they all need to be treated slightly differently in terms of our obligation to 'realize the commercial value of the asset'.

Thank you in advance for your help- if you could please have summaries to me by Oct 11- we can get them to TOM before his meeting with JH-

Suzy

Tom- please confirm that this timing meets your quarterly update needs- thank you.

Suzanne A. Lebold, Ph.D.
Senior Director, Scientific and Strategic Assessment
Global Pharmaceutical Licensing and Business Development
Abbott Laboratories
Phone: (847) 937-1436 Fax: (847) 937-1771
email: suzanne.a.lebold@abbott.com

Abbott Laboratories
Project Overview – ABT 518 - CLOSED

Title: ABT 518 (previously in Ph I)

Deal Type: WW Out-license asset

Background: ABT 518 is a matrix metalloproteinase (MMP) inhibitor program which represents a novel therapeutic class with the potential to alter the way cancer is treated by preventing or modifying disease progression and / or metastases for solid tumors.

Abbott has contacted several companies with little interest to date.

Origination: Due to two other MMP failures in the market (therapeutic window did not occur prior to toxicity (caused severe joint pain) it was decided that this program was too risky. ABT 518 may have promise as the efficacy of has been shown to occur prior to toxicity.

Patent: Approx 2018

Contacts:

Company	Contact	CDA	Status
Chiron	Lauren Miller	??	- No interest
Duke University	Dr. Herb Hurwitz	In process	- No interest on behalf of ABT; Duke wants for free
Paramount Capital	Jeffrey Solash	??	- No interest on behalf of ABT; Paramount interested in option agreement
Salmedix	Alan Rosenthal	Yes	- No interest
Sunesis	Akiko	Yes	- No interest

Time Line / Action Plan:

August	ABT valuation of asset
Sept	ABT presentation of confidential data
Sept	ABT Terms sheet to perspective buyers
Oct	ABT selection of final partner / due diligence
Nov / Dec	Contract negotiation / execution

Team Members: John Fitz Gerald
Jerry Wenker
Jane Hoff-Velk
Perry Nisen / Development
Steve Fesik / Research

[DATE]

1 of 2

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ABBT334840

Abbott Laboratories
Project Overview – ABT 518 - CLOSED

Legal / Others

Additional Time: Medium (Preparation of slides for presentation, due diligence and contract negotiation).

Deal Terms:

- Upfront, development and regulatory milestones payable to ABT
- Royalties on net sales

Other:

- Spending to data and patent being looked into

[DATE]

2 of 2

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ABBT334841

Leonard Deposition Exhibit 49

P's Exhibit BH



Jane A
Hoff-Smith /LAKE/PPRD/ABB
OTT

09/15/2005 12:49 PM

To: Suzanne Lebold/LAKE/PPRD/ABBOTT@ABBOTT
cc: Gayle A Kirkpatrick/LAKE/GPRD/ABBOTT@ABBOTT
bcc
Subject: Re: Update on ABT-518 []

Suzy:

There are no commercial rights granted to Vanderbilt. Abbott has rights nonexclusively WW to Institution Inventions and the option for an exclusive WW license with royalty rate to be negotiated.

The history behind the initiation of these studies was a visit by Perry Nisen and Moma Vidakovic to Dr. Matrisian's lab at Vanderbilt. She is a leader in the field of MMP inhibitors and she expressed an interest in studying ABT-518. Nothing was/has been decided with respect to if the results were positive.
Jane

Suzanne Lebold

Suzanne Lebold

09/15/2005 12:37 PM

To: Jane.Hoff-Smith@abbott.com
cc: Gayle A Kirkpatrick/LAKE/GPRD/ABBOTT@ABBOTT
Subject: Re: Update on ABT-518 []

are there any commercial rights in the MTA- or is it for research purposes only?
If the results were positive- would we pick the program back up for anything, or is this purely an academic exercise.

Just want to characterize activities on the asset.

Thanks

Jane A Hoff-Smith



Jane A Hoff -Smith

09/15/2005 12:31 PM

To: Suzanne Lebold/LAKE/PPRD/ABBOTT@ABBOTT
cc: Gayle A Kirkpatrick/LAKE/GPRD/ABBOTT@ABBOTT
Subject: Update on ABT-518

Suzy:

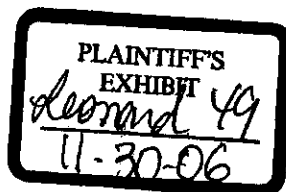
Gayle indicated you needed an update on the ABT-518:

1. Amendment to original MTA was just completed with Dr. Lynn Matrisian at Vanderbilt to extend the agreement term to 10/21/06
2. Protocol did not change because it was never completed- they had difficulty breeding the specific mouse model required for the studies.
3. The studies will be initiated as soon as they have enough mice to run them.

If you need anything else, please just let me know.

Jane

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ABBT372504

Leonard Deposition Exhibit 50

P's Exhibit NE

John M
Leonard/LAKE/PPRD/ABBOTT
TT

04/15/2002 06:10 PM

To: Thomas J Lyons/LAKE/PPRD/ABBOTT@ABBOTT, Stan
Bukofzer/LAKE/PPRD/ABBOTT@ABBOTT

cc:

bcc:

Subject Re:

The Hancock response that Jeff wants:

John M. Leonard, M.D.
Vice President
Global Pharmaceutical Drug Development
Global Pharmaceutical Research and Development
PH: (847) 938-4545
FX: (847) 937-3918
Vickie Enders, Admin. (847-935-1905)

----- Forwarded by John M Leonard/LAKE/PPRD/ABBOTT on 04/15/2002 06:10 PM -----

Jeff M Leiden

04/15/2002 04:39 PM

To: John M Leonard/LAKE/PPRD/ABBOTT@ABBOTT

cc:

Subject Re: []

I think we should tell them that we are

1. reviewing the Ketek situation re size of safety database
2. Carrying out additional ph I studies of QT and hepatotoxicity at request of FDA to assess class effects of Ketolides
3. Analyzing existing phII and phIII results for impact on label and market opportunity

That we expect this analysis to be complete by June July and at that point we will be in a position to make a decision on if and how to proceed with additional phIII development
We will keep them in the loop as our analysis proceeds

Jeff

Jeffrey M. Leiden MD PhD
President and Chief Operating Officer, Pharmaceuticals
Chief Scientific Officer
Abbott Laboratories
Dept 0392, BLDG AP6D
100 Abbott Park Rd
Abbott Park, IL 60064-6020

Phone: 847-938-9313
Fax: 847-937-2632
email: jeff.leiden@abbott.com

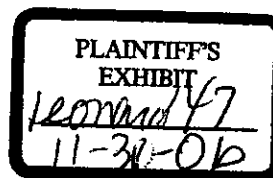
John M Leonard

John M Leonard

To: Jeff M Leiden/LAKE/CORP/ABBOTT@ABBOTT
cc:

Confidential

ABBT225709



FOR I.D. 6/1/07 100
EXHIBIT 50

04/15/02 07:55 AM

Subject:

Two quickies: In case you did not hear it, we were cleared by FDA to enter women in all the .695 studies so we are back where we wanted to be.

Second, and more important, we own Hancock an update. How do you want to handle the 773 communication? We can say that we are analyzing data and have slowed down (as we have been saying externally), but if the questioning goes deeper, we will need a plan as the status will evolve quickly.
J

John M. Leonard, M.D.
Vice President
Global Pharmaceutical Drug Development
Global Pharmaceutical Research and Development
PH: (847) 938-4545
FX: (847) 937-3918
Vickie Enders, Admin. (847-935-1905)

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ABBT225710

Leonard Deposition Exhibit 51

P's Exhibit ID



Jeanne M
Fox/LAKE/PPRD/ABBOTT
11/20/2000 04:11 PM

To John M Leonard/LAKE/PPRD/ABBOTT@ABBOTT, Jerald J
Wenker/LAKE/PPD/ABBOTT@ABBOTT, Lawrence E
Roebel/LAKE/PPRD/ABBOTT@ABBOTT
Arthur J Higgins/LAKE/PPD/ABBOTT@ABBOTT, Carl
Craft/LAKE/PPRD/ABBOTT@ABBOTT, George
Aynilian/LAKE/PPRD/ABBOTT@ABBOTT, Reid
Patterson/LAKE/PPRD/ABBOTT@ABBOTT, Julia Y
Hui/LAKE/PPRD/ABBOTT@ABBOTT, William M
Bracken/LAKE/PPRD/ABBOTT@ABBOTT, Maria M
Paris/LAKE/PPRD/ABBOTT@ABBOTT, Joaquin M
Valdes/LAKE/PPRD/ABBOTT@ABBOTT, David D
cc Morris/LAKE/PPRD/ABBOTT@ABBOTT, Jie X
Zhang/LAKE/PPRD/ABBOTT@ABBOTT, Carol S
Meyer/LAKE/PPRD/ABBOTT@ABBOTT, Robert K
Flamm/LAKE/PPRD/ABBOTT@ABBOTT, Linda E
Gustavson/LAKE/PPRD/ABBOTT@ABBOTT, Gregory
Bosco/LAKE/PPRD/ABBOTT@ABBOTT, Rod M
Mittag/LAKE/PPD/ABBOTT@ABBOTT, Linda J
Swanson/LAKE/PPRD/ABBOTT@ABBOTT, Cheryl D
Spencer/LAKE/PPRD/ABBOTT@ABBOTT

bcc

Subject FDA Telephone Contact Report ABT-773

Attached is a contact report for a teleconference that was held with FDA today concerning ABT-773. We are now officially on clinical hold until further discussion at the End-of-Phase 2 meeting scheduled for November 27, 2000.

Call me if you have questions,

jeanne



FDA Contact Reportdoc.doc

CONFIDENTIAL
ABBT0558681

Leonard EXHIBIT 51
FOR I.D. 6/1/07 1.0ef

FDA Contact Report

Compound/Product Discussed: ABT-773 Date of Contact: November 20, 2000
 Application Type & Number: IND 57,836

	Name & Title	Group
FDA Person(s) Contacted	Dr. Janice Soreth, Acting Division Director	Division of Anti-Infective Drug Products
	Dr. Mercedes Albuerno, Supervisory Medical Officer	
	Dr. Alma Davidson, Medical Officer	
	Dr. Bob Osterberg, Supervisory Pharm/Tox Reviewer	
	Dr. Terry Peters, Pharm/Tox Reviewer	
	Maureen Dillon-Parker, CSO	
	Jeanne Fox	Regulatory Affairs
Abbott Representatives	Greg Bosco	"
	Carl Craft	Venture
	George Aynilian	"
	Reid Patterson	Drug Safety
	Bill Bracken	"
	Julia Hui	"

Subject of Call: FDA requested this teleconference to talk about some "toxicology issues" prior to our End-of-Phase 2 meeting scheduled for next week (November 27, 2000).

Report of Call: The meeting began with introductions, then Maureen said she was filling in for our CSO, Jose Cintron, and asked if we had been told the subject of the call. I told her we understood the purpose to be tox, but had no specifics. Dr. Peters then began by saying that she reviewed our 3 month monkey toxicology study as well as the inspection report and has several concerns about the study. First, there is a concern because the FDA investigator found that there was active drug in some of the control samples. Second, they have knowledge which they cannot share with us regarding similar drugs that has convinced them that the monkey is not a sensitive enough species to look for the two primary toxicities they are worried about with macrolides and ketolides, hepatotoxicity and QT changes. They had advised us of their recommendation that we use the dog after the results of the one month monkey tox study, and now they are looking at a 3 month study in monkeys that they believe is flawed. Reid explained the rationale behind not using the dog since our early work in dogs indicated that emesis became so pronounced in dogs that we were unable to reach significant drug exposures, therefore we switched to monkeys. They asked whether we had done QT assessment in this study and we responded no, that our QT evaluation was done by the safety pharmacology group. They responded that they were looking for QT assessment on multiple dosing in toxicology studies, not the kind of information that came out of single dose pharmacology studies. They then stated that to meet the requirement to start phase 3, they need chronic toxicology done in two species and so they want us to do a 30-day dog study with full QT assessment done by telemetry and evaluation for hepatotoxicity. I pointed out that we have provided in our pre-meeting package specific analyses of both our hepatic safety evaluations and our QT monitoring results from the 900 plus patients that we have treated in Phase I and 2. Reid stated that since nothing significant was seen in any of the human data it would seem somewhat meaningless to go back and do the dog study. FDA asked to put us on hold.

When they came back after 5 minutes they said they would propose a compromise, and instead of a 30 day study, they would require a two week dog study with special emphasis on hepatotoxicity and QT, with telemetry and with a

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recovery period. We agreed that it may be possible to run such a study, although we still have concerns about getting adequate exposures in the dog. I then said that our bigger concern was allowing this tox request to delay our phase 3 studies, and asked if it would be acceptable to run the tox study concurrently since the Phase 3 studies had already started. Based on FDA's reaction it was clear they were unaware that we have begun our studies. Dr. Soreth asked how we could do that prior to our end-of-phase 2 meeting. I pointed out that we had first requested a meeting in July, and it has been scheduled and rescheduled several times. I referenced the letter I sent to her in October when they cancelled the scheduled meeting the last time, which told her we would begin our trials the second week in November. I also referred to the new protocol amendments that were submitted over the last several weeks initiating the studies. She said they expected us to send the protocols to them and wait for comments before proceeding. I explained that we have received comments on at least one of the protocols and parts of the others. She wanted to know if our recent submissions stated we were planning to enroll patients now. I responded that these are our standard study start-up submissions that include information on a minimum of one investigator who can then enroll patients. I explained that we have several patients currently enrolled. Dr. Soreth was not happy with this information, and FDA put us on hold again.

When FDA came back off hold Dr. Soreth told us that they were not expecting us to begin our phase 3 studies prior to the end-of-phase 2 meeting, and that they want us to suspend enrollment at this time. In other words, we are now on clinical hold with these studies. They will discuss this information further prior to the meeting next Monday. I asked whether the 1 hour that has been allotted us next Monday will be enough. Dr. Soreth responded that it will have to be. She indicated they are probably still going to require a dog study. I commented that we do have in writing from Dr. Peters that the three-month study in monkeys should be acceptable to fulfill the requirement. We received this in response to our argument against using dog when they first raised it last year. They did not have the reviewers document in front of them, and Dr. Peters could not recall it, so they said they would go back and look through their records. She also stated that regardless, they would still have issues with the quality of the 3 month study. Reid promised to provide a written response to the issue of active drug in control samples, stated again that there was nothing significant enough to invalidate the study, and questioned whether we could get the exposures they were looking for in dogs. Dr. Peters commented that other sponsors with drugs like these manage to do dog studies. We agreed to provide an estimated timeline for a two-week dog study at Monday's meeting.

We suggested to Dr. Soreth that they also review the QT and hepatic safety assessments that were done in phase 2 since those were done at doses up to 600 mg, so there is more exposure in those phase 2 studies than we will have in phase 3. She said they will look at it.

Action Items: Provide a chronology showing all of the delays in getting the phase 2 meeting to happen as well as the submission of the protocols for review and the response from Dr. Peters acknowledging the 3 month monkey study as acceptable. Prepare a written response regarding the positive study drug in controls from the 3 month tox study.

Leonard Deposition Exhibit 52

P's Exhibit NC



Pharmaceutical Licensing & New Business Development

FROM: James L. Tyree
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TO: Jeff Leiden

Date: February 13, 2002

cc: Global Pharmaceutical Licensing & New Business Staff

C. Begley
B. Dempsey
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R. Gonzalez
B. Kamen
J. Leonard
D. Norbeck
E. Oguro
S. Murphy
S. Weger
T. Fieyeman
M. White
L. Wyatt

RE: January 2002 HighlightsI. CONCLUDED BUSINESS

Project Lead (Co-dev): Abbott has elected to terminate further negotiations with Novartis for the co-development of LAF237 for Type II Diabetes following extensive discussions.

Lilly's Opioid Antagonists (License): This opportunity was declined due to insufficient patent life (composition of matter).

Emisphere Oral Heparin (License): Due diligence on this Phase III opportunity was conducted in January. The review with senior management confirmed the decision not to proceed with further discussions for this product based on the due diligence results.

II. PENDING FINAL RESOLUTIONNegotiations

Uprima-Japan: Exclusive rights for Uprima in Japan are being negotiated with Takeda. The agreement is targeted for execution by the end of February.

Project Galleon (Co-promo/Acquisition): Negotiations for the co-promotion of Gatiloxacin (quinolone) in EU are ongoing with Grunenthal. Negotiations are expected to be finalized by the end of February. A Gatiloxacin acquisition analysis has been initiated for the US. Valuation analysis of various deal structures will be presented to senior management by the end of February.

TET (Gene Regulation Technology, Divestiture and Licensing): Divestiture: ABC sent a letter to all parties who requested confidential packages, indicating Abbott's preferred bid structure. Dellagen has sent an offer of \$15MM, comprised of cash and non-cash considerations to purchase the asset including all revenues from existing licensees. All bids are due mid-February and the next steps will be determined pending the offers. Commercial licenses: Cell Genesys, Ceregene, CellFactors, and Virxys have expressed interest in non-exclusive commercial licenses to the technology. ABC has drafted term sheets for these companies and has scheduled teleconferences to discuss these terms.

Yeast Display (Out-Licensing): Introductory letters announcing Abbott's acquisition of the yeast display technology were sent out to about 20 companies expressing interest in the technology. After receiving introductory letters, both Maxygen and Zymogenetics have expressed interest in further discussing licenses to the technology.

Due Diligence

Project Zeus (Divestiture): A non-binding term sheet was received from Virbac for the purchase of Zeus assets. Due diligence is scheduled for February 14-15.

Project Thunderbird (Acquisition): An assessment is underway for the acquisition of Tequin, BMS's quinolone in the US. Estimated peak sales in the US could reach greater than \$700MM by 2007.

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Project Blue Sun (Divestiture): Abbott is in the process of divesting the worldwide Selsun shampoo business. Management presentations are scheduled for early February. Abbott requires at least twice the sales or \$80MM in order to continue the process. HSR needs to be submitted by late February or early March in order for Ross to achieve Q102 recognition of the gain. A1 gain may be taken beyond Q2 with the potential of 2008 carryover due to registration issues.

Project Dakota (Partnering): Abbott is in the process of finding a partner to maximize D2E7 in comprehensive promotional and clinical development collaboration. Disease areas under consideration include rheumatoid arthritis; Crohn's disease; psoriasis; psoriatic arthritis and others. A meeting was held with Novartis in New Jersey on February 7. Novartis' proposal will be reviewed with senior management mid-February to define the next steps.

Triangle Strategic Overview: A presentation reviewing the original Triangle deal expectations, their current product portfolio valuation, an outline of strategic options, and a recommendation will be submitted to senior management in February. Of the four potential drugs in development at Triangle, the focus of the analysis is on Coviracil (FTC) and DAPD and the potential combination product with Gilead's Tenofovir (Project Geometry). A worldwide co-promotion of a combination product Tenofovir (an approved drug) and Coviracil (FTC) for HIV (not yet approved) is financially modeled based upon a 70/30 profit split. Discussions with Gilead on the combination are advancing with regulatory and clinical data regarding Coviracil being provided to Gilead by Triangle.

Project Garden (Divestiture): Abbott is analyzing the divestiture of Gengraf. Discussions are proceeding with Sangstat. A number of other parties have declined interest in acquisition.

Hydra (Equity and Research Collab): A non-binding term sheet containing equity terms and milestones for two research collaboration agreements that include option rights to products has been proposed. The two research collaborations involve the elastin oligopeptide-coated stent project in the prevention of restenosis and the CatSper ion channel for potential in male infertility and/or contraception.

Pending Go/No-Go Decision

Gilead Tenofovir (License): FTC combination product commercial assessment and business discussions on-going. Further technical assessment has been deferred pending the outcome.

Project Gladiator (Acquisition): The analysis of the GSK Anesthesia business in Europe & PAA is being updated. A go/no-go decision is pending final due diligence and commercial analysis.

Biogen (Amevive) Project Acorn (Co-promo): A co-promotion of Amevive for psoriasis in Latin America has been modeled based upon preliminary deal terms. Biogen concerns center on potential conflict with D2E7 in psoriasis market. A go/no-go decision is scheduled for mid-February.

Lundbeck (S-citalopram, Co-promo): A co-promotion of the S-citalopram, an SSRI anti-depressant in Latin America is being financially modeled. Meeting scheduled with Lundbeck 2/13 to discuss deal model/terms. Next step: evaluate forecast/terms in model for go/no-go.

Project Rhythm (Co-promo/mkt): A co-promotion / co-market of P&G's Azimilide for CV antiarrhythmia (worldwide ex-Japan) has been modeled based upon preliminary deal terms. A go/no-go decision is scheduled for mid-February, pending commercial support in bringing forward based on forecast/estimated deal terms and impact.

Chiron HCV IP (License): Negotiations are continuing for non-exclusive rights to two targets for drug discovery.

Myriad Novel Depression Genes/Targets (Collaboration): Negotiations for a definitive agreement are ongoing with a target for execution by February 28th. A Press Release is being routed for approval.

III. NEW INITIATIVES

Taisho (Overview): Prepared a comprehensive overview of Taisho for senior management meeting with Taisho, 2/15.

ABT-773 (Partnering): Taisho has been informed of the decision to stop the global development of ABT-773 except for the Japan market place. A strategy for the partnering of ABT-773 is being developed and will be reviewed with management at the end of February.

ICOS IC485 (License): Technical discussions w/ICOS regarding this PDE-4 inhibitor that is in Phase I for RA scheduled for February.

ABT-598 (Outlicense): Presented deal terms to Icagen who indicated they would not make any cash upfront payment for the asset (urinary incontinence DDC asset). Discussions with Icagen have concluded and an outlicensing package is being drafted.

TAT Licensing Process: The TAT teams have developed a list of licensing opportunities based on the LRP. The LSP will be finalized at the end of February.

Abbott's Licensing and Business Development Web Site: An external web site was developed and presented to senior management which markets Abbott's businesses, research focus and targeting biotech companies, venture capitalists and universities, to access novel targets and technologies. The web site address is <http://Licensing.Abbott.com> and the email address Licensing@Abbott.com will be launched in March.

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P's Exhibit IO

ABT-773 Update February 12, 2001**Introduction**

ABT-773 is a ketolide antimicrobial, an evolutionary step from the macrolide antimicrobials such as erythromycin and the new generation macrolides like clarithromycin and azithromycin. It is in phase III development as a replacement to clarithromycin.

The antibiotic market is a large market (\$20.5 Billion in 1999) and is expected to expand on a global sales basis (\$26.5 Billion in 2005). The majority of the markets sales are in the oral tablet/capsule segment. Market sales increases are being driven by replacement of older/cheaper agents with branded agents. Zithromax has driven market demand for cost/convenience/tolerability, while the quinolones (Levaquin, Tequin, Avelox) are the fastest growing segment, playing into resistance concerns. Resistance is a major driving force for both the quinolones and ketolides development.

Ketolides are a Novel Class of Antimicrobial

- Active includes key respiratory tract infection pathogens including macrolide and penicillin resistant *S. pneumoniae* and *S. pyogenes*
- Bactericidal activity
- Prolonged post antibiotic effect
- Reduced resistance development

ABT-773 is the most active ketolide presently under development. It is 5 to 10 times more active than telithromycin (Aventis ketolide) against *S. pneumoniae* and *S. pyogenes* including resistant strains. It has equal activity to telithromycin and azithromycin against *H. influenzae*. The increased activity can be attributed increased ribosomal binding. Compared to macrolides that bind only to domain V, ABT-773 binds to both domains II and V. The binding is essentially irreversible and provides bactericidal activity against *S. pneumoniae*.

Key issues facing the ABT-773 development program are summarized below**QTc Issues**

The potential for QTc prolongation is currently a prominent issue facing drug development across therapeutic areas-worldwide. Antimicrobial agents including macrolides and quinolones are of concern to regulatory agencies. There is considerable scientific uncertainty in relating the findings from in vitro assays and animal models to clinical risk of malignant arrhythmias. In an effort to gain more

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knowledge these agencies are requiring the pharmaceutical companies to do additional test including

- ICH guidelines require data from animal models and 200 patients
- FDA is in the process of evaluating all drug class known to have a potential for prolonging QTc (erythromycin and clarithromycin)
- FDA has question whether ketolides behave like macrolides
- FDA requested additional dog tox work to evaluate QTc of ABT-773
- ABT-773 studies required including ECG monitoring in pivotal Phase 3 studies.
- FDA may require a Phase I study in patients with underlying cardiac disease, but the design for these studies has not been determined.
- Some antimicrobials now contain warnings for QT prolongation such as moxifloxacin.
- Telithromycin (Ketek) data residing at FDA will be reviewed by FDA Advisory Committee at a meeting scheduled for May 2001 probably related to concerns about efficacy and not related to QTc concerns.

The ketolide ABT-773 will be considered guilty until proven innocent because it is related to erythromycin and clarithromycin which are also suspect and under scrutiny. ABT-773 has the following data related to its potential or lack of potential to affect the QT interval.

- Preclinical data positive for QTc dose response.
- A possible dose effect in Phase I at total daily dose ≥ 800 mg.
- No significant QT effect observed when ABT-773 was administered with the metabolic inhibitor ketoconazole. (Increased ABT-773 C_{max} 5X)
- No concentration response in Phase I studies (≤ 300 mg).
- No consistent QT effect observed at clinical doses studied in Phase IIB studies. (150 mg QD to 600 mg QD)

The Venture plan for dealing with the uncertainties related to developing a drug which has an unknown potential for prolonging the QT intervals is to pro-actively attempt to find out as much about our drug and the science related to QTc by;

- Completed preclinical evaluation of ABT-773
- Initiate FDA recommended dog studies.
- Completed ECG monitoring of >200 patients in Phase II and III
- Continue to monitor QTc and electrolytes in Phase III programs.
- Perform FDA requested study of QTc in patients with pre-existing cardiac disease; perform phase I study as required by CPMP.
- IV ABT-773 Phase I study will monitor QTc carefully
- Consult with Drs. Morganroth and Moss QTc advisors.

Liver Toxicity Issues

The FDA has similar concerns regarding the potential for liver toxicity of new drugs as it has for QTc issues, since both of these problems have resulted in

drugs being removed from the market shortly after approval. The concerns have been directed at the quinolones, but all antimicrobials are under going extensive evaluations. The FDA has a meeting on guidance to industry on how to study the potential for liver toxicity, scheduled for February 11-12, 2001. Jean Fox will attend this meeting and report back on it so that we will be able to update this topic at the February meeting.

In the Japanese bridging study run in Hawaii we saw increases in LFTs in Japanese subjects. This was very disturbing, since increases in LFTs were seen only in the Japanese subjects. In addition the Japanese subjects had AUCs which were 50% higher than the western subjects. LFTs in over 1000 western subjects did not show any problems. Since, the Japanese subjects with elevated LFTs did not show a dose response, it was felt that the changes in LFTs might be related to the high caloric diet on the unit. To answer this question Phase I food interaction and a repeat of the bridging study was preformed in Japan. The results of this study showed no evidence of any problem with LFTs in the Japanese or Caucasians. Based on the encouraging results we will continue moving forward with the Japan Program.

Phase III Tablet Program

The Phase III tablet program is underway after several delays related to manufacturing of the 150 mg tablet to replace the 300 mg tablets and the late date (11/27/00) of the FDA End of Phase II meeting. The present plan is to complete the Phase III 150 mg once daily indications in the US and Europe this year. These studies include two pharyngitis studies compared to penicillin 500 mg TID, one ABECB study in the US compared to Azithromycin, and one European ABECB study compared to Levofloxacin. The CAP and sinusitis dose selections studies are running globally, but no European sites are enrolling yet due to the changes in the protocol following the FDA End of Phase II meeting. We are increasing sites and planning to go to the Southern Hemisphere if needed to complete the studies before the start of the fall respiratory season. These changes have added additional costs that will add approximately \$5.0 MM to the budget.

The results of the CAP and Sinusitis studies have the potential of generating divergent development paths based on differences in AI and PPD regulatory and commercial considerations. PPD would prefer to have 150 mg once daily for all indications and AI would prefer 150 mg once daily for pharyngitis and ABECB and 150 mg BID for CAP and sinusitis. Once we complete the study we will need to meet to iron out the possible options.

ABT-773 IV Formulation Program

The IV formulation program is presently unfunded. The IV program is important to overall program because of the following;

- Hospital formulary acceptance
- XX% share gain in Tab sales due to step-down therapy
- Positions 773 for serious infections
- Support for *S. pneumoniae* resistance claim
 - FDA indicated that bacteremic patients will be important to establish body of evidence for this claim
- Provide additional information on QTc effects

The ABT-773 IV program received partial funding last year both from PPD and HPD, but has not been funded for 2001. The following outlines the IV program fund and funding needed.

- PPD/HPD Collaboration initiated 9/99
- PPD funded Program 01/00-08/00 (\$1.4MM)
 - Formulation development (lactate salt, lyophilized powder)
 - Animal pain models
 - Two week Tox study (monkey)
- HPD funded Program 08/00-12/00 (\$0.8MM)
 - Two week Tox study (rat)
 - Clinical supplies for Phase I
 - Stability program
- 2001 funding
 - HPD first pass funding cut for 773 IV (\$7MM)
 - Milestone funding to Phase I Go/No Go (\$1MM)
- Total program development costs 2000 - 2003 (\$22.5MM)

The clinical program with 2001 funding decision in February will included;

- | | |
|--|---------|
| • Single Dose-rising Phase I study | Apr/01 |
| • Multiple Dose Phase I with selected dose | June/01 |
| • File US IND | Oct/01 |
| • Initiate Phase III | Dec/01 |
| – 2 step-down CAP studies (US/Europe) | |
| – 2-3 days dosing | |
| – Two seasons to complete | |
| • Filing | Aug/03 |

The Venture would recommend funding the Phase I study to determine safety and tolerability profile as a GO/No Go decision. Assuming a GO decision we would need \$7 MM 2001 to start Phase III program.

Pediatric Program

The pediatric suspension program is on hold. ABT-773 is 5 to 7 times more bitter than clarithromycin. This will make the development of an acceptable formulation very difficult. The first prototype tested had a taste that was better than clarithromycin but not as good as azithromycin. The pharmacokinetics showed AUCs that were only 70% of the tablet formulation. Even with the difficulties of making an acceptable formulation the pediatric formulation would have benefits including increasing the perception of safety, better pricing and acceptance in European markets, and FDA requires studies in pediatrics. The Venture would recommend continuing the hold until we resolve other issues and then re-evaluate possible ways of overcoming the taste problem.

Japan Development Program

The Japan development program is planned in coordination with Taisho and Dainabot. Taisho funds 10.69% of global development costs and 50% of local Japan costs. The Venture is attempting to use a bridging strategy as the primary plan for development in Japan. The Phase I studies in Japan which were initiated in response to the LFT problems in the first bridging study, have been completed. There were not increases in the LFTs of the Japanese or Caucasians in the study. We will be meeting with Taisho and Dainabot to formulate a plan to present to Kiko in the 2nd or 3rd Quarter.

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February 2001

ABT-773

Monthly Highlights – Key Project Progress

- All Phase III U.S. studies are actively enrolling patients. Drug releases have started for the European studies with 9 sites ready to enroll in CAP, 3 sites in ABS, 21 sites in ABECB and 11 sites in ASP. No patients have been enrolled in Europe since the initial drug shipments have been made (within the last 2 weeks). We are expecting enrollment in all four studies at any time. All sites are being very carefully managed to get them actively enrolling patients as soon as possible.
- Further Phase III start up activities are ongoing in Central America, So Africa and So America for CAP and ABS for their winter seasons starting in May. As we proceed with the enrollment in the Northern Hemisphere during March and April, we will make a firm decision on initiating these sites for enrollment to be as cost effective as possible.
- The initial Phase I study for the IV formulation will go ahead and is planned to start in early May. This study will enable us to evaluate the appropriate IV dose and evaluate injection site pain with the formulation prior to a Multiple Dose study. Timing for Phase I Go/No Go by September is critical if we would like to have an IV filing within a year of the tablet filing.
- The CMC and Biopharm End of Phase II package was submitted to FDA on March 1st to request a meeting in April. Meeting preparations are in progress.
- A CMC planning meeting with Taisho and Dainabot is scheduled for March 7 and 8th to discuss the timing and requirements for the Japanese Phase II/III clinical supplies and Japanese NDA filing requirements to include these activities in the Abbott Park and U.K. CMC plans.
- A team review was held to discuss all data gathered on the pediatric formulation prototypes. The final taste testing comparing 773 to clari and azi suspensions indicated that the 773 prototype had a better taste than the clari suspension. A follow up meeting will be held with the franchisee to discuss further interest in pursuing a pediatric formulation.

Next Quarter's Key Progress Markers

Key Progress Marker	Target Date
Hold CMC/Biopharm End of Phase II meeting with FDA.	04/30
Determine if Southern Hemisphere sites for CAP and ABS should be initiated as a contingency if US/European enrollment fails to meet 500 patient target.	04/30
Complete enrollment in CAP and ABS Dose selection studies to meet Dose Decision milestone in July, assuming US/Europe can meet 500 patient target.	06/01
Complete enrollment in ASP and ABECB comparator studies in the U.S.	06/01
Complete intermediate scale-up activities in the U.K. site for initial bioequivalence study between Abbott Park and U.K. mfg sites.	05/31
Initiate first Phase I study of IV formulation.	05/01
Results available for Japan Phase I Dose Ranging study to determine Japan dose for Phase II/III studies and potential Bridging strategy.	04/15
Hold Abbott/Taisho meeting to discuss Japan Phase I results and propose Phase II/III clinical plans to discuss with KIKO.	05/08

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Key Project Issues and Risks

Risk or Issue	Potential or Known Impact Check all that apply and Describe Impact	Strategy / Progress	Area / Responsibility	Resolution Date Planned / Actual
A change in bulk drug physical or chemical properties during formulation development.	<input type="checkbox"/> Cost <input checked="" type="checkbox"/> Time <input type="checkbox"/> Profile <input type="checkbox"/> Regulatory Delay in the Aug 2002 filing date. If at the 1200L scale, a delay of up to 18 months.	A strategy for the bulk drug lots that will be used in the NDA formulation runs will be reviewed with the CMC Technical Committee in early December. Bulk drug properties and granulation variables are being evaluated as a means to develop appropriate physical specifications for the bulk drug.	SPD/PARD	12/2001
Clinical enrollment challenges due to a) delay in end of phase II meeting from September to November at request of FDA b) delay in start of study due to protocol changes requested by FDA c) light 2000-01 flu/respiratory season	<input checked="" type="checkbox"/> Cost <input checked="" type="checkbox"/> Time <input type="checkbox"/> Profile <input checked="" type="checkbox"/> Regulatory Critical path trials to development timeline are CAP & sinusitis, with dose decision for these indications needed by 7/2001 to maintain current timeline. Current estimates are that 7/2001 decision will be met.	Meeting with FDA was held on November 27 th . Protocol amendments have been signed off incorporating all FDA requested changes and implemented in the U.S. and Europe. Additional sites added in Europe and southern hemisphere to make up for delays. The team is working to overcome the challenges as much as possible by closely managing clinical sites in the U.S. and Europe, as well as planning for contingency sites in the Southern Hemisphere. A decision to initiate the Southern Hemisphere sites will be made in April as a contingency should the US and Europe fail to meet enrollment targets for CAP and sinusitis. ASP and ABECB studies are not on the critical path. Current estimates are that 7/2001 decision will be met.	Venture	7/2001
150 mg QD vs BID dose decision in CAP/sinusitis.	<input checked="" type="checkbox"/> Cost <input checked="" type="checkbox"/> Time <input checked="" type="checkbox"/> Profile <input checked="" type="checkbox"/> Regulatory Current AI opinion is that QD may receive regulatory challenge for approval in CAP unless data is very compelling given PK profile of 150 mg QD; however, BID dosing, while relatively minor commercial impact ex-US, represents significant commercial hurdle in US.	Decision must be made in light of QD vs BID CAP and sinusitis data (7/2001); DSG analysis is planned to facilitate decision; internal efforts to defend 150 mg QD dosing with data on potent ribosome binding properties of ABT-773 are ongoing by Discovery, with an advisory planned with external experts Aug 2001 to define further study.	Venture/NPD/DSG	7/2001

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February 2001

ABT-773

Key Project Issues and Risks

Risk or Issue	Potential or Known Impact Check all that apply and describe impact	Strategy / Progress	Area / Responsibility	Resolution Date Planned / Actual
Regulatory uncertainties over how to deal with the ketolide/macrolide class regarding QT interval effects.	<input type="checkbox"/> Cost <input type="checkbox"/> Time <input checked="" type="checkbox"/> Profile <input checked="" type="checkbox"/> Regulatory Additional studies could be required to show no effects on QT. Class labeling could negatively impact sales of the product.	QT effects are the current hot topic for the FDA, and were reflected in the changes they requested to the Phase III program. FDA concern is whether ketolides behave like macrolides and whether there may be a class effect. FDA requested an acute tox study in dog to further evaluate cardiac effects and also discussed whether a Phase I study should be conducted in subjects with underlying cardiac disease. ECG monitoring will be done in all Phase III studies with the exception of the ASP study in Europe.	Regulatory	6/2002/
Definition of starting materials for the bulk drug (at what step in the manufacturing process) will affect our ability to continue with process improvements necessary to continue to reduce the cost of the bulk drug. This has cost implications up to 3 years post-launch.	<input checked="" type="checkbox"/> Cost <input type="checkbox"/> Time <input type="checkbox"/> Profile <input type="checkbox"/> Regulatory Ability to define step 5 as the starting material will allow us to make further process improvements to reduce the cost of the bulk drug.	The End of Phase II CMC meeting with FDA will be requested for January 2001 to present the package on starting material definition for step 5 intermediate. Meeting is targeted for the end of March. The end of Phase II package outlining our plans for starting materials was submitted to FDA on March 1.	SPD	04/2001
The pharmacokinetic profile of QD dose could receive regulatory challenge or be viewed as sub-optimal commercially, particularly with respect to H. influenzae.	<input type="checkbox"/> Cost <input type="checkbox"/> Time <input checked="" type="checkbox"/> Profile <input checked="" type="checkbox"/> Regulatory Support by PK/PD experts is important for positioning this product in the marketplace. Competitors may challenge ABT 773 efficacy without expert support for the efficacy model.	Phase I/b studies indicated efficacy with 150 mg daily dose in ABECB and ABS. PK/PD data together with ribosome kinetics support the decision to proceed with 150mg QD in mild infections (ABECB and ASP) and select between 150mg BID and 150mg QD in CAP and ABS. Recent PK/PD data support AUC of 1-6 for clinical exposure in CAP necessary for cure. Dose decision for CAP & sinusitis expected 7/2001. To address this issue and potentially create a new model for evaluating PK/PD, internal efforts to characterize ribosome binding properties are ongoing by Discovery, with an advisory planned with external experts Aug 2001 to define further study.	Venture/NPD	07/2001

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February 2001

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Key Project Issues and Risks

Risk or Issue	Potential or Known Impact Check all that apply and Describe Impact <input type="checkbox"/> Cost <input type="checkbox"/> Time <input checked="" type="checkbox"/> Profile <input type="checkbox"/> Regulatory	Strategy / Progress	Area / Responsibility	Resolution Date Planned / Actual
Obtain sufficient quantity of clinical isolates with resistant organisms to request a separate claim for activity against resistant <i>S. pneumoniae</i> .	<input type="checkbox"/> Cost <input type="checkbox"/> Time <input checked="" type="checkbox"/> Profile <input type="checkbox"/> Regulatory Without a sufficient number of isolates, we will not obtain a claim based on clinical results for activity against resistant pathogens. Will need to rely on in vitro data only to support this claim.	FDA feedback regarding a resistance claim for PRSP is that a sufficient "body of evidence" needs to be gathered to convince them to grant a claim. They estimate >10 resistance isolates will be required. CAP and ABECB isolate requirements need further clarification, but ABS isolates are evaluated separately. They are not convinced about the clinical significance of MRSP and need further evidence. They suggest that an IV formulation to obtain bacteremic patients and more severe CAP infections will enhance the probability of obtaining the claim. The Phase I study to evaluate the IV formulation prototype will initiate in May 2001.	Venture	06/2002
Due to the dose change in the base development program, Phase I will be repeated in Japan to further evaluate dose-ranging. An increase in liver enzymes was observed in the low and medium dose groups of Japanese volunteers in the first study in Hawaii, and will be further evaluated in the Phase I studies done in Japan. A Japanese dose and formulation, as well as the Phase I/III studies, will be defined once the dose-ranging has been completed. This plan will determine the filing date for Japan.	<input checked="" type="checkbox"/> Cost <input checked="" type="checkbox"/> Time <input type="checkbox"/> Profile <input checked="" type="checkbox"/> Regulatory	The Japan Phase I Dose-Ranging study was completed in February and drug analysis is ongoing. No increases were seen in ALT/AST, with all values within the normal range. Based on these results, ABT-773 is clear in terms of hepatotoxicity profile and the liver enzyme abnormality observed in Hawaiian Ph I with Japanese population was seen as a result of the high fat diet during the study period. The Japanese BAL study will start in April. Dose selection and BAL results need to be available prior to a meeting with Kiko to discuss the Phase II/III strategy. The current decision is to proceed to the KIKO meeting once Phase I results are available and a dose selection decision has been made for CAP and ABS based on the US/European studies. Preliminary BAL results may be available in August.	Japan	08/2001/

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February 2001

ABT-773

Key Project Issues and Risks

Risk or Issue	Potential or Known Impact Check all that apply and Describe Impact	Strategy / Progress	Area / Responsibility	Resolution Date Planned / Actual
The initial development of an IV formulation has been completed and clinical supplies have been manufactured by HPD. Full development of the IV formulation has not been committed.	<input checked="" type="checkbox"/> Cost <input type="checkbox"/> Time <input type="checkbox"/> Profile <input type="checkbox"/> Regulatory Phase I will proceed to a Go/No Go decision based on initial milestone funding.	HPD funding for 2001 (\$7MM) is no longer approved. At the ABT-773 Portfolio meeting, Jeff Leiden committed to find funding (approx. \$1MM) to do the Phase I studies for the IV in 2001 to enable us to evaluate the viability of the formulation in terms of pain on injection and the dose requirements. Decision was made by John Leonard to proceed with the initial Dose Ranging Phase I IV study. This is planned for early May. A Go/No go decision on the IV formulation is planned for Sept. 2001.	HPD, Venture	09/2001

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ABT-773

Key Activities

Commercial		LBE	Actual
Activity			
Completion of study tracking intranet		1001	
Integration of intranet into communication plan		2001	
Integration of intranet into draft product label		2001	
Identification of communication vendor		2001	
Submission of brand/USAN names		2001	
Preliminary qualitative positioning research		4001	
Quantitative market research to support revised forecast		4001	
Preliminary qualitative positioning research		4001	

Formulation		Plan	Actual
Activity			
Phase I Formulation (Caps)		12/1997	12/1997
Phase II Formulation (Tablet)		7/1998	8/1999
Clinical Supplies Phase IIB		7/1998	8/1999
Phase III Formulation (Tablet)		4/2000	7/2000
Phase III Clinical Supplies Manufactured		9/2000	9/2000
NDA Lots (3) Completed		7/2000	01/2001
Completion of 1 Year Stability for NDA		8/2001	
Formulation Peer Review		11/2001	

Drug Substance

Drug Substance		KG	Plan	Actual	Actual Projected Cost/kg
Activity					

See the Following page for a summary of Bulk Drug deliveries in SPO.

Toxicology		Plan Start 7/98	Actual Start Date	Report Completed
Activity				
2-week oral Rat/Monkey		7/1997	6/1997	9/1998
Acute Studies		8/1997	8/1997	12/1997
Mouse Lymphoma/Micronucleus		11/1997	11/1997	4/1998
1 Month Rat/Monkey		12/1997	12/1997	12/1998
Pregnant Rat/Rabbit RF		1/1998	1/1998	11/1998
SEG II Rat/Rabbit		3/1998	3/1998	2/1999
Guinea pig sensitization		11/1998	11/1998	2/1999
3 Month oral Rat/Monkey		9/1999	10/9/1999	8/2000
Seg VIII Rat		9/1999	10/8/1999	12/2000
IV Initiation studies, set 1		7/1999	7/15/1999	8/1999
IV Initiation studies, set 2		2/2000	2/2000	3/2000
IV 2-week Rat/Monkey Studies		6/2000	6/2000	01/2001
Neonatal/Juvenile Rat		10/1999	11/1999	7/2000

* Target cost of drug substance at launch is \$2,500/kg (Finished Product)

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February 2001

ABT-773

SPD ABT-773 Bulk Drug Deliveries Update

	Target Date	Amount	Delivery Date	Amount	Lot #	Amount after milling
Campaign 1	2/28/99	200 Kg	2/23/99	209 Kg	50-007-CA-00	207.5 Kg (2/26)*
Campaign 2a	6/15/99	140 Kg	6/17/99	131 Kg	54-702-NI-00	129.4 Kg (6/19)*
Campaign 2b	7/15/99	140 Kg	7/21/99	121.5 Kg	55-208-CB-00	119.3 Kg (8/4)*
Tox lot	8/30/99	5 Kg	8/25/99	6.1 Kg	55-718-NI-00	
Campaign 3a	9/30/99	160 Kg	10/8/99	170.5 Kg	58493CB00	138.4 Kg (10/16)*
Campaign 3b	10/21/99	160 Kg	10/11/99	176.5 Kg	58494CB00	169.5 Kg (10/16)*
Pilot run 1	-----	15 Kg	10/30/99	18.9 Kg	59763N100	no milling
Pilot run 2	-----	15 Kg	2/5/00	15.5 Kg	61790NI00	no milling
Pilot run 3	-----	25 Kg	1/30/00	27.5 Kg	62764CB00	27.3 Kg (4/18)*
Campaign 4	12/10/99	320 Kg	11/23/99	355 Kg	61741CB00	309 Kg (3/2)*
Campaign 5	12/30/99	300 kg	12/16/99	300.5 Kg	60665CB00	289.2 Kg (3/3)*
Campaign 6	2/28/00	280 Kg	2/23/00	321 Kg	62796CB00	315.5 Kg (3/6)*
Campaign 6 (IV)	2/28/00	15 Kg	2/22/00	20 Kg	62797CB00	18 Kg (3/15)*
Campaign 7	3/30/00	300 Kg	4/10/00	370 Kg	63890CB00	361.2 Kg (4/18)*
Campaign 7 (IV)	3/30/00	5 Kg	3/29/00	19 Kg	63889CB00	17.2 Kg (4/11)*
Campaign 8	4/25/00	200 Kg	5/11/00	263 Kg	64970CB00	256.5 Kg (5/15)
Campaign 8 (IV)	4/25/00	15 Kg	4/25/00	19.8 Kg	64971CB00	17.7 Kg (5/11)*
Campaign 9	6/15/00	300 Kg	6/14/00	375.7 Kg	65084CB00	355.7 Kg (6/20/00)
Campaign 9 (IV)	6/15/00	15 Kg	6/5/00	18.1 Kg	65065CB00	16.7 Kg (6/9/00)*
Campaign 10	7/15/00	300 Kg	7/26/00	361.2 Kg	67176CB00	359.0 Kg (8/10/00)
Campaign 11	8/15/00	300 Kg	8/4/00	333.7 Kg	68285CB00	271.9 Kg (9/7/00)
Campaign 12	10/6/00	300 Kg	9/27/00	356 Kg	69458CB00	292.3 Kg (12/8/00)
Campaign 13	11/23/00	300 Kg	11/15/00	351.2 Kg	71665CB00	349.1 Kg (12/20/00)
Total (year 2000)						2,815.5 Kg
Campaign 14	1/28/01	300 Kg	1/26/01	327.5 Kg	73886CB00	318.9 Kg (2/13/01)
Campaign 15	2/10/01	330 Kg	1/14/01	354.9 Kg	71699CB00	353.8 Kg (2/02/01)

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February 2001

ABT-773

• Weight after rework

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ABT-773

All Clinical Studies:

Protocol Number	Phase	Study Name	Start 1 st PL Dosed	End (Last CRF In)	Patients		Protocol Number	Phase	Study Name	Start 1 st PL Dosed	End (Last CRF In)	Patients	
					Target	Current						Target	Current
M89-048	II	Dose Ranging, ABECB	9/1/99	3/31/00	300	384							
M89-053	II	Dose Ranging, Sinusitis	9/1/99	4/30/00	300	282							
M89-054	II	Dose Ranging CAP	9/1/99	4/30/00	300	187							
M00-219	III	CAP, Dose Ranging	11/7/00	4/30/01	800	127							
M00-216	III	ABECB vs Azithromycin	11/7/00	4/30/01	600	230							
M00-217	III	ABECB vs Levofloxacin	11/7/00	4/30/01	500	0							
M00-225	III	Sinusitis Dose Ranging	11/7/00	4/30/01	600	180							
M00-223	III	Pharyngitis vs Penicillin 250mg TID	11/7/00	4/30/01	520	300							
M00-222	III	Pharyngitis vs Penicillin 500mg TID	11/7/00	4/30/01	520	0							

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ABT-773

Ongoing Clinical Studies (List first time in man, Phase II Dose-Ranging and Pivotal Trials)

Protocol:

Objective:

ABT-773 Doses:

Comparator Doses:

Target Enrollment:

Status:

Major Findings:

M00-219 – Dose-Ranging CAP

Dose selection.

150mg QD vs 150mg BID, 10 days

None

800

Currently enrolling

M00-216 – Phase III ABECB vs Azithromycin

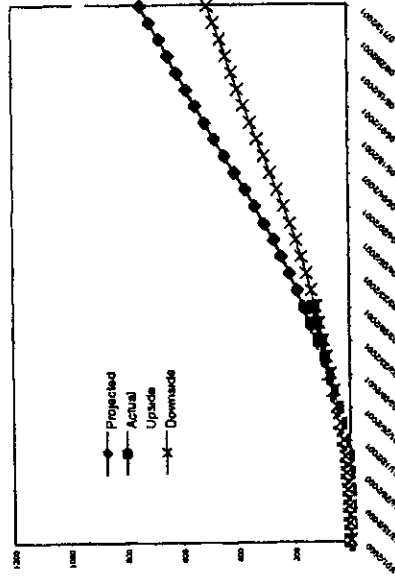
Safety & Efficacy

150mg QD, 5 days

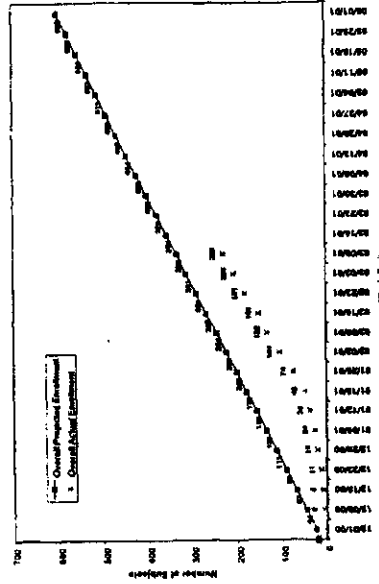
Azithromycin 500mg day 1, 250mg QD for 4 days

600

Currently Enrolling



Author:
(Double click on chart to edit)



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ABT-773

Ongoing Clinical Studies (List first time in man, Phase II Dose-Ranging and Pivotal Trials)**Protocol:****Objective:****ABT-773 Doses:****Comparator Doses:****Target Enrollment:****Status:****Major Findings:****M00-217 - Phase III ABECB vs Levofloxacin**

Safety & Efficacy

150 mg QD

Levofloxacin 500mg QD for 7 days

500

Enrollment not yet started.

M00-225 - Sinusitis Dose-Ranging

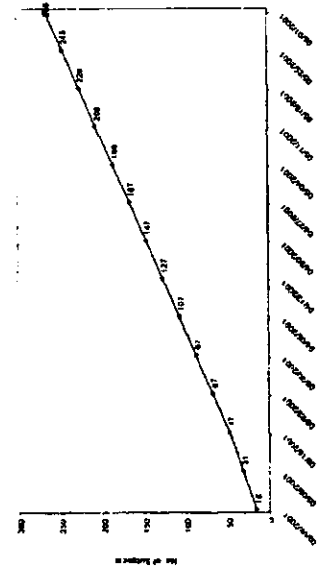
Dose Selection

150mg QD vs 150mg BID, 10 days

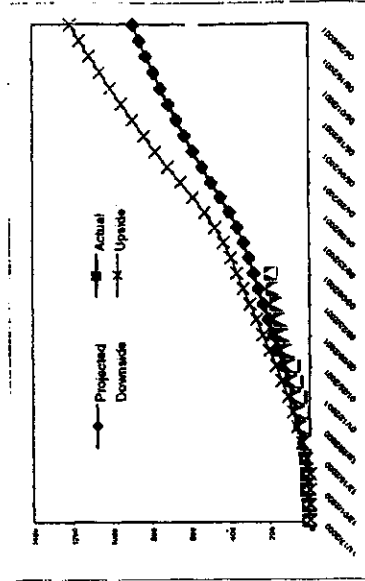
None

600

Currently enrolling



Author:
(Double click on chart to add)



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ABT-773

Ongoing Clinical Studies (List first time in man, Phase II Dose-Ranging and Pivotal Trials)**Protocol:**

M00-223 - Phase III Pharyngitis vs Penicillin 500mg TID

Objective:

Safety & Efficacy

ABT-773 Doses:

150mg QD., 5days

Comparator Doses:

Penicillin 500 mg TID, 10 days

Target Enrollment:

520

Status:

Currently enrolling

Major Findings:

M00-222 - Phase III Pharyngitis vs Penicillin 500mg TID

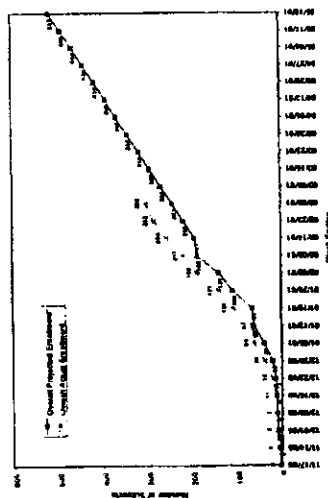
Safety & Efficacy

150mg QD. 5 days

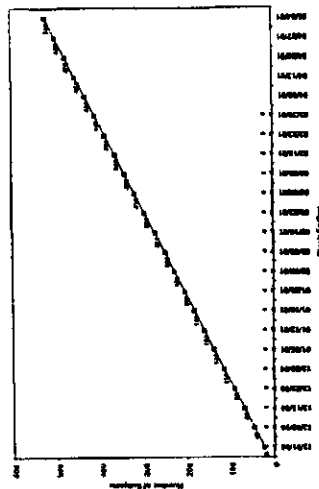
Penicillin 500mg TID, 10 days

520

Sites initiated, enrollment not yet started



Author:
(Double click on chart to edit)



D477Z:\MPSRs\ABT-773.doc

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Leonard Deposition Exhibit 57

P's Exhibit FC

CH-228011-049-MADRAS/jjrd

BUILDING A WORLD OF OPPORTUNITIES TOGETHER



Development portfolio review kick-off
March 7, 2001

Leopard EXHIBIT 57
FOR I.D. 6/1/07 107

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MCK 00377

CH-228011-049-MADRAS/lbrd

STRUCTURE OF PRESENTATION

PAGE NOT TO BE INCLUDED IN PRESENTATION

J. Leiden

Slides

- Introduction (page 2)
 - Who "we" are (page 3)
 - Objectives (page 4)
 - Decision-making approach (page 5)
-
- Ground rules (page 6)
 - Agenda (pages 7-9)

J. Leonard

CH-228011-049-MADRAS/jbrd

INTRODUCTION

- Our goal is to be the world's premier health care company
- Together we must build a leading, global R&D portfolio by leveraging our
 - Outstanding scientists
 - Exciting technologies
 - Scale
 - Global reach
- This unified portfolio review process is the first step in achieving our goal
 - Success will require tough choices

CH-228011-049-MADRAS/jbrd

WHO "WE" ARE – COMBINED STRENGTH

People

- Total employees 70,700
- Number of scientists 5,400

Pipeline

- Preclinical >30
- In development 46
 - Phase 1 16
 - Phase 2 17
 - Phase 3 13
- Filed 5

Capabilities

- Total facilities 156
- Manufacturing sites 67 worldwide
- Global pharmaceutical R&D investment ~\$950 million

CH-228011-049 MADRAS/jbrd

OBJECTIVES FOR THIS WEEK'S REVIEW MEETING

- To gain a shared understanding of all development projects across the new company
- To identify the critical issues, timelines, and upcoming decisions for each project, emphasizing
 - Clinical
 - Commercial merits
- To provide senior management with the technical inputs necessary to make portfolio decisions over the coming weeks

CH-228011-049-MADRAS/BRD

DECISION-MAKING APPROACH GOING FORWARD

What

- Classify products into three groups
 1. Projects to definitely retain
 2. Projects warranting further discussion/assessment
 3. Projects which will not be retained

When

- Initial list of projects in the third group will be communicated within 1-2 weeks
- All other projects to continue as planned until final prioritization completed by early May

How

- Single uniform process across the combined portfolio
- Consistent set of criteria to evaluate all project opportunities

CH-228011-049-MADRAS/jbrd

MEETING GROUND RULES

Presenters

- Provide fact-based, objective perspective on the project
 - Focus on most important issues (given time constraint)
 - Identify critical milestones and funding requirements
 - Propose the product plan and give your rationale
- Stay for presentations within own individual therapeutic area/venture groups

Audience

- Ask questions of clarification during the time allocated for discussion
- Respect time constraints
- Maintain strict confidentiality of the material presented

CH-228011-049-MADRAS/jbrd

AGENDA – WEDNESDAY, MARCH 7

	Welcome/Introduction Meeting objectives	Presentation 10 minutes 10 minutes	Discussion	Presenter J. Lelden J. Leonard
7:30 a.m. 7:40 a.m.				
7:50 a.m. 8:15 a.m.	Anti-infectives ABT-492 HSR-903	20 minutes 30 minutes	5 minutes 10 minutes	C. Craft T. Hirose/R. Krauthmeier
8:55 a.m.	Anti-virals Triangle projects • HIV and HBV (FTC; DAPD)	30 minutes	10 minutes	M. Health-Chlozzi
9:35 a.m.	<i>Morning Break</i>			
9:55 a.m.	Urology BSF 42027 (ETA/BPH)	30 minutes	10 minutes	M. Luz/U. Legler
10:35 a.m.	Asthma Hokunalin tape	15 minutes	5 minutes	T. Hirose/R. Krauthmeier
10:55 a.m. 11:30 a.m.	Oncology ABT-510 ABT-751	20 minutes 20 minutes	15 minutes 15 minutes	P. Nisen P. Nisen
12:05 p.m.	<i>Lunch</i>			
1:05 p.m. 1:25 p.m. 1:50 p.m. 2:15 p.m.	ABT-518 Rubitecan Theragyn ABT-627	15 minutes 20 minutes 20 minutes 30 minutes	5 minutes 5 minutes 5 minutes 10 minutes	P. Nisen P. Nisen P. Nisen P. Nisen
2:50 p.m.	<i>Afternoon break</i>			
3:15 p.m.	Cardiology Darusentan (LU 135252) and other ETAs	30 minutes	10 minutes	M. Luz/U. Legler
3:55 p.m. 4:35 p.m. 5:15 p.m.	Thrombosis PEG-hirudin Ancord Urokinase/Pro-urokinase	30 minutes 30 minutes 30 minutes	10 minutes 10 minutes 10 minutes	V. Ifthekar/U. Legler N. Bender S. Gupta

CH-228011-049-MADRAS/jbrd

AGENDA – THURSDAY, MARCH 8

		Presentation	Discussion	Presenter
7:30 a.m.	Neuroscience	30 minutes	10 minutes	B. McCarthy
8:10 a.m.	ABT 594	15 minutes	15 minutes	Granneman/Doan/Bell
8:40 a.m.	ABT-963	30 minutes	10 minutes	B. Rendenbach-Mueller/B. Hargan
9:20 a.m.	BSF 201640			
	BSF 74398 (Parkinson)	30 minutes	10 minutes	
10:00 a.m.	<i>Morning Break</i>			
10:20 a.m.	Dilaudid OROS	45 minutes	15 minutes	B. Gold/R. Krauthelmer
11:20 a.m.	BSF 190555 (Schizophrenia)	30 minutes	10 minutes	B. Rendenbach-Mueller/B. Hargan
12:00 p.m.	<i>Lunch</i>			
1:00 p.m.	Hydrocodone	10 minutes	10 minutes	Abbott (TBD)
1:20 p.m.	Bimoclonol (ABT-822)	30 minutes	10 minutes	B. Wallin
2:00 p.m.	Gastro-enterology	15 minutes	5 minutes	S. Dawe/R. Krauthelmer
2:20 p.m.	Ganaton (pro-kinetic)	30 minutes	10 minutes	T. Hirose/ R. Krauthelmer
3:00 p.m.	TU-199 (proton pump inh.)	20 minutes	5 minutes	T. Hirose/ R. Krauthelmer
3:25 p.m.	AU-224 (colon pro-kinetic)			
	<i>Afternoon break</i>			
3:45 p.m.	Phase III Projects	30 minutes	15 minutes	C MacLeod
4:30 p.m.	Levosimendan	30 minutes	15 minutes	A. Pethö-Schramm/U. Legler
5:15 p.m.	Rythmol SR DZE7	45 minutes	30 minutes	C. Splegler/E. v. Borcke

CH-228011-049-MADRAS/jbrd

AGENDA – FRIDAY, MARCH 9

	Phase III (Continued)	Presentation	Discussion	Presenter
7:30 a.m.	Segard	45 minutes	15 minutes	L. Daum/E. v. Borcke
8:30 a.m.	J695	30 minutes	10 minutes	R. Janocha/E. v. Borcke
9:10 a.m.	Clivarine	30 minutes	15 minutes	F. Misselwitz/U. Legler
9:55 a.m.	<i>Morning break</i>			
10:15 a.m.	ABT-773	30 minutes	15 minutes	C. Craft
11:00 a.m.	Phase IV Projects			
11:20 a.m.	Clarithromycin	15 minutes	5 minutes	C. Olson
11:40 a.m.	Omnicef	15 minutes	5 minutes	C. Olson
12:00 p.m.	Kaletra	15 minutes	5 minutes	E. Sun
	Norvir	15 minutes	5 minutes	E. Sun
12:20 p.m.	<i>Lunch</i>			
1:20 p.m.	Meridia (Sibutramine)	15 minutes	5 minutes	E. Chong/W. Hargan
1:40 p.m.	Uprima	15 minutes	5 minutes	S. Bukotzer
2:00 p.m.	Trandolapril (patch, intervention trials)	15 minutes	5 minutes	B. Rendbach-Mueller/ U. Legler/N. Bender
2:20 p.m.	Fenofibrate	15 minutes	5 minutes	D. Yannicelli
2:40 p.m.	Depakote	15 minutes	5 minutes	K. Sommerville
3:00 p.m.	Gengraf	15 minutes	5 minutes	T. Japour
3:20 p.m.	Conclusion			J. Lelden

Leonard Deposition Exhibit 58

P's Exhibit PH

INITIAL PORTFOLIO PRIORITIZATION

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
Anti-infectives ABT-492	C	<ul style="list-style-type: none"> Address safety issues (including QTc) with internal/ expert review Determine how many indications at launch (pay back) 	• J. Leonard	-
HSR-903	T	<ul style="list-style-type: none"> Consider trading with Dalichi Halt any new expenditure 	• J. Tyree	-
ABT-773	C	<ul style="list-style-type: none"> Assess side effects issues with expert review (QTc and liver tox.) Ensure all drug interactions are adequately covered Assess relative to Ketek 	<ul style="list-style-type: none"> • J. Leonard • J. Leonard • I. Loew 	-
Urology BSF 420627	P	<ul style="list-style-type: none"> Set up task force to address issues and bring back plan to senior management Reasons for failure of the SKB ETa/b antagonist Design short (~4 week) PoP trial for symptom relief Rationale for sustained release formulation Nature of the Schwarz Pharma relationship 	• J. Leonard	• By May
Hypothyroidism T3/T4	P	<ul style="list-style-type: none"> Assess most appropriate ratio Gain FDA feedback on study design Determine ex-US market attractiveness (price) 	• J. Leonard	• By May
Asthma Hokunalin tape	P	<ul style="list-style-type: none"> Conduct market research on acceptance by different patient segments Determine how to position against long acting beta agonists and combination Inhalers Evaluate opportunity to gain complete access to the patch technology 	<ul style="list-style-type: none"> • A. Higgins/ E. Fiorentino • J. Tyree 	• May

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Leonard, EXHIBIT 58
FOR I.D. 6/1/07 1 aef

INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
Oncology				
ABT-510	C	<ul style="list-style-type: none"> Pursue proof of concept Leverage TAP knowledge of angiogenesis product development (appropriate endpoints) 	• Project team	• As planned
ABT-751	C	<ul style="list-style-type: none"> Pursue proof of concept Use echocardiogram to monitor potential cardiotoxicity Resolve potent drug manufacturing approach 	• Project team	• As planned
ABT-518	Hold	<ul style="list-style-type: none"> Wait for May results from Pfizer (will save ~\$1mill) and re-evaluate Halt all further expenditure 	• Senior management	• May
Rubitecan	P	<ul style="list-style-type: none"> Significant clinical rework required (funded by partner)- further in-depth review required Make a proceed decision when 2Q data available 	• J. Leonard	• By May
Theragyn	P	<ul style="list-style-type: none"> Negative initial scientific perspective - further in-depth review required, e.g., <ul style="list-style-type: none"> Determine if there is a PoC to support claim Address GMP issues Determine best control to demonstrate efficacy Re-look at partnership contract 	• J. Leonard	• By May
ABT-627	C	<ul style="list-style-type: none"> Seek alternative funding (e.g., NCI) before starting major trial If move ahead <ul style="list-style-type: none"> Determine how to ensure NDA filing in 2004 Get FDA input since survival not primary endpoint Harmonize US and EU study design and inputs Consider partnership (e.g., BI or established oncology player) 	<ul style="list-style-type: none"> • J. Tyree • J. Leonard, P. Nisen • J. Tyree 	<ul style="list-style-type: none"> • By May • ASAP • By May

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INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
Cardiology/ thrombosis Darusentan (LU 135252)	Hold	<ul style="list-style-type: none"> • Continue currently budgeted funding for next 6 months • Do not start any new trials (e.g., hypertension planned for May) • If proceed, plan for pilot to look at effects in sperm and tetragonality • Consider out-license or swap 	<ul style="list-style-type: none"> • Project team • J. Tyree 	<ul style="list-style-type: none"> • Ongoing • ASAP
LU 208075	Hold	<ul style="list-style-type: none"> • Continue currently budgeted funding for next six months • Look at Myogen deal • Out-license or swap 	<ul style="list-style-type: none"> • Project team • J. Tyree 	<ul style="list-style-type: none"> • ongoing
Levosimendan	C	<ul style="list-style-type: none"> • Conduct detailed expert panel review for trial design 	<ul style="list-style-type: none"> • J. Leonard 	<ul style="list-style-type: none"> • May
PEG-hirudin	P	<ul style="list-style-type: none"> • Set up expert panel for commercial assessment (is diabetes an option?) 	<ul style="list-style-type: none"> • E. Ogunro 	<ul style="list-style-type: none"> • By May
Anicard	T	<ul style="list-style-type: none"> • Identify out-licensing opportunities 	<ul style="list-style-type: none"> • J. Tyree 	<ul style="list-style-type: none"> • TBD
Urokinase	P	<ul style="list-style-type: none"> • Market research required on open cath • Match versus tPA in dose-ranging studies to determine efficacy 	<ul style="list-style-type: none"> • E. Fiorentino 	<ul style="list-style-type: none"> • By May
Pro-urokinase	C	<ul style="list-style-type: none"> • Identify opportunities to speed up program 	<ul style="list-style-type: none"> • Project team 	<ul style="list-style-type: none"> • TBD
Clivarine	C	<ul style="list-style-type: none"> • Assessment by HPD (review previous evaluation and new trial data) • Understand finished product manufacturing cost 	<ul style="list-style-type: none"> • E. Ogunro • B. Dempsey 	<ul style="list-style-type: none"> • By May
Rythmol SR	C	<ul style="list-style-type: none"> • Continue filing • Verify if package is likely approvable • Assess commercial attractiveness in a generic market 	<ul style="list-style-type: none"> • Project team 	<ul style="list-style-type: none"> • Ongoing

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INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
Neuroscience				
ABT 594	P	<ul style="list-style-type: none"> • Await results from ongoing PII trial – probable T • Project team to develop decision criteria for go/no go 	<ul style="list-style-type: none"> • Senior management 	<ul style="list-style-type: none"> • June/ July
ABT 963	C	<ul style="list-style-type: none"> • Identify a co-development/co-promotion partner (TAP high on list) • Evaluate benefits of the long half life in pain and cancer (including additional physician market research) • Explore cancer prophylaxis and Alzheimer's indications 	<ul style="list-style-type: none"> • J. Tyree • Project team 	<ul style="list-style-type: none"> • TBD
BSF 201640	P	<ul style="list-style-type: none"> • Complete review of all schizophrenia NCEs with expert panel • Complete staffing of internal project team, but halt further expenditure beyond looking at hepatic tox. and QTc • Understand Novartis contract and level of interest 	<ul style="list-style-type: none"> • I. Loew • Project team • J. Tyree 	<ul style="list-style-type: none"> • By May
BSF 190555	P	<ul style="list-style-type: none"> • Complete review as above • Halt further expenditure pending outcome 	<ul style="list-style-type: none"> • I. Loew 	<ul style="list-style-type: none"> • As above
BSF 74398	C	<ul style="list-style-type: none"> • Allow DevCo to continue development • Re-look at relationship with DevCo 	<ul style="list-style-type: none"> • Project team • J. Tyree 	<ul style="list-style-type: none"> • By May
Dilaudid Oros	Hold	<ul style="list-style-type: none"> • Return to ALZA or out-license to other interested partner 	<ul style="list-style-type: none"> • J. Tyree 	<ul style="list-style-type: none"> • TBD
Hydrocodone	C	<ul style="list-style-type: none"> • Assess regulatory pathway • Understand DEA impact on manufacturing 	<ul style="list-style-type: none"> • Project team 	<ul style="list-style-type: none"> • By May
Bimoclomol (ABT 822)	P	<ul style="list-style-type: none"> • Await data from ongoing trial in April before deciding whether to continue - probable T • Halt further expenditure pending outcome 	<ul style="list-style-type: none"> • Senior management 	<ul style="list-style-type: none"> • April

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INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
Gastro-enterology				
Ganalon	P	<ul style="list-style-type: none"> • Conduct U.S. commercial assessment with TAP • Assess how to position in Europe versus generics and implications for comparative trial • Develop model to assess spend at different termination points 	<ul style="list-style-type: none"> • E. Fiorentino • Bob Funck 	<ul style="list-style-type: none"> • By June • By May
TU-199	T	<ul style="list-style-type: none"> • Terminate outside Japan 	• Project team	• Immediate
AU-224	C	<ul style="list-style-type: none"> • Develop and pursue a small PoC trial in humans ASAP (consider niche indication first and leverage Marlene's expertise) • Conduct market research on IBS versus constipation (including pricing) 	<ul style="list-style-type: none"> • Project team • E. Fiorentino 	• ASAP
Immunology				
D2E7	C	<ul style="list-style-type: none"> • Conduct intensive product review <ul style="list-style-type: none"> - 2 day meeting with J. Lennard's group (already in process) - 1/2 day session with senior management group • Important actions include <ul style="list-style-type: none"> - Approach FDA for fast track and compassionate use - Develop strategy for DMARD claim in first submission - Assess need for Enbrel assay to detect HAHA's - Assess delivery device options - Evaluate additional indications (e.g., Psoriasis, Crohns, heart failure) and pediatric program - Profile Celltech product - Assess impact of additional IV program on reimbursement • Develop list of potential marketing partners for quids 	<ul style="list-style-type: none"> • J. Leonard • Various • J. Tyree 	<ul style="list-style-type: none"> • By May • By May

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INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
Immunology (continued) Segard	Hold	<ul style="list-style-type: none"> • Continue filing in EU and Canada • Put on hold in US – consider creating a small team in the US to analyse data, propose smaller PII study • Research pricing, marketing and Phase IV plans in Europe • Look at TNF-alpha levels retrospectively to see stratification with IL-6 • Assess manufacturing strategy • Identify potential out-licensing opportunities (Genentech) 	<ul style="list-style-type: none"> • Project team • J. Lechard 	• Ongoing
J695	P	<ul style="list-style-type: none"> • Decide on most attractive indications from Abbott and partner perspective • Discuss with partner ways to share the various indications and potential for TNF-alpha combinations • Add commercial person to the project team by this week 	<ul style="list-style-type: none"> • J. Tyree • E. Fiorentino • J. Tyree • Ongoing 	• ASAP

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INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- continue
P- pending
T- terminate

Project	Priority	Next steps	Responsibility	Timing
PIV programs				
Clarithromycin	C	• None identified	-	-
Omnicef	C	• Talk to partners	• J. Tyree	-
Kaletra	C	• None identified	-	-
Norvir	C	• None identified	-	-
Meridia	Hold	<ul style="list-style-type: none"> • Conduct commercial assessment for CNS and depression (P&L) • Assess combination therapy with fibrates • Assess outcomes trial design to meet preferred commercial profile; determine payback 	<ul style="list-style-type: none"> • B. Dempsey, J. Amott, E. Fiorentino • Project team 	• ASAP
Uprima	C	• Ensure no redundant trials with TAP in Europe	• Project team	• Ongoing
Trandolapril patch	T	• Halt all activities	• Project team	• Immediate
Trandolapril "invest" clinical program	P	• Review trial in more detail (reduce complexity and risk)	• E. Fiorentino	• By May
Other trandolapril trials	C	• Continue "Create", "Peace" and "Benedict" trial programs	• Project team	• Ongoing
Fenofibrate	C	• Develop co-formulation ideas with Meridia and statins (including assessment of sales and costs)	• Project team	-
Depakote	C	• None identified	-	-
Gengraf	C	• None identified	-	-

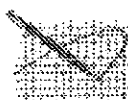
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Leonard Deposition Exhibit 64

P's Exhibit IW



Marleen H
Verlinden/LAKE/PPRD/ABB
OTT

03/31/2001 09:50 PM

To Eugene X Sun/LAKE/PPRD/ABBOTT@ABBOTT

Carl Craft/LAKE/PPRD/ABBOTT@ABBOTT, Stan

Bukofzer/LAKE/ABBOTT@ABBOTT, Richard G

cc Granneman/LAKE/PPRD/ABBOTT@ABBOTT, John M

Leonard/LAKE/PPRD/ABBOTT@ABBOTT

bcc

Subject Re: ABT-773

For what they are worth, here are my summary thoughts on the way forward with -773, QT issue:

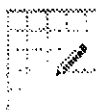
- despite significant issues with the quality of the QT data collection to date, a QT signal has emerged from both the pre-clinical and clinical programs.
- The numbers of patients with ECG data suffices to establish that there probably is an issue (i.e. N=200= criteria for exposing enough patients, in order not to miss a signal as laid out in CPMP guidelines) have been met as hundreds of patients have had ECG data and a signal was indeed found
- the remaining question to be solved then is: what is the size of the QT effect ? and what is the size not only in healthy volunteers but also in patients at risk (defined in guidelines). The quantification entails a dedicated, super -defined experimental design (see QT project), with PBO, the therapeutic dose, a 3-5 times higher dose (600 mg, and potentially an arm with normal dose in presence of ketoconazole. Serial ECGs to be taken and rigorous timing of ECGs with detailed dose-response directed pK-pD analysis, XO design with subjects being own control. Because of the quality issue with QT data collected to date, the size of the QT effect might actually be larger than would appear from the current data.

For the populations at risk I would recommend considering that such patients be included in Phase III pivots and that in these subgroups, very standardized QT collection and reading be undertaken (as if it were a Phase I trial)

Hope this helps

Marleen

Eugene X Sun



Eugene X Sun
03/30/2001 04:36 PM

To: Carl Craft/LAKE/PPRD/ABBOTT@ABBOTT, Joaquin M Valdes/LAKE/PPRD/ABBOTT@ABBOTT, Maria M Paris/LAKE/PPRD/ABBOTT@ABBOTT, Marleen H Verlinden/LAKE/PPRD/ABBOTT@ABBOTT, Perry D Nisen/LAKE/PPRD/ABBOTT@ABBOTT, Efraim Shek/LAKE/PPRD/ABBOTT@ABBOTT, Reid Patterson/LAKE/PPRD/ABBOTT@ABBOTT, Xavier Frapaise/LAKE/ABBOTT@ABBOTT, Jeanne M Fox/LAKE/PPRD/ABBOTT@ABBOTT, Jennifer J Moore/LAKE/ABBOTT@ABBOTT, Nigel Livesey/LAKE/ABBOTT@ABBOTT, David D Morris/LAKE/PPRD/ABBOTT@ABBOTT, Margaret A Foley/LAKE/PPRD/ABBOTT@ABBOTT, Carol Olson/LAKE/PPD/ABBOTT@ABBOTT, Helen B Ellopoulos/LAKE/PPRD/ABBOTT@ABBOTT, Dawn M Carlson/LAKE/PPRD/ABBOTT@ABBOTT, Linda E Gustavson/LAKE/PPRD/ABBOTT@ABBOTT, Walid Awn/LAKE/PPRD/ABBOTT@ABBOTT, Bryan F Cox/LAKE/PPRD/ABBOTT@ABBOTT, Gary A Gintant/LAKE/PPRD/ABBOTT@ABBOTT, Jie X Zhang/LAKE/PPRD/ABBOTT@ABBOTT, Thao T Doan/LAKE/PPRD/ABBOTT@ABBOTT, Stan Bukofzer/LAKE/ABBOTT@ABBOTT, Richard G Granneman/LAKE/PPRD/ABBOTT@ABBOTT, Carol S Meyer/LAKE/PPRD/ABBOTT@ABBOTT

cc: John M Leonard/LAKE/PPRD/ABBOTT@ABBOTT

Subject: ABT-773

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ABBT0571202

Leonard EXHIBIT 64
FOR I.D. 6/1/07 1.00f

Summary and followup items from this morning's discussion on the potential for QT prolongation by ABT-773:

1. Europe:

The accumulated phase VII data, as well as expected phase III data, will be assessed in the context of the CPMP guidance to determine to what extent the guidance has been met, and what additional clinical studies or clinical data, if any, are needed. This will be a joint effort of venture, AI regulatory, PK, and statistics.

2. FDA:

Although the FDA has expressed interest in seeing data from patients with cardiac compromise, it is not clear how this study would be conducted. It was mentioned that such studies were requested of Sepracor for norastemizole. It would be instructive to get further information on this if available. The Ketek advisory scheduled for 4/26 should provide some indication of the direction FDA will take with this class of drugs on this particular issue. The relevant groups will reconvene following this advisory.

3. Several outside experts in the field and with potential US and European regulatory insights will be contacted in the next several weeks. A package of data should be prepared and made available to them in advance, necessary CDA's prepared, and a block of time allocated to specifically discuss ABT-773. These advisors (and Abbott contacts) are Shah (Bryan), Malik (Marleen), Moss and Morganroth (venture). Meetings with these individuals should be coordinated such that the appropriate scientific, medical, and regulatory personnel are in attendance.

Thank you to those who prepared presentations this morning

Leonard Deposition Exhibit 65

P's Exhibit FR

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Resource Allocation Across GPRD



Abbott Laboratories

Discussion document

May 5, 2001

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FOR I.D. 6/1/07 1007
EXHIBIT 65

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MCK 00204

CH-CH-228013-013j/aaRD

CONTENTS

- Synergy targets and opportunities identified to date

- Potential savings by TA and project in development
- Potential savings by TA and project in discovery
- Functional area and site budgets
- Decision templates
- Appendix


CH-CH-228013-013[p/aaRD

SUMMARY

- Synergies* of \$63 million required in 2001 and \$79 million in 2002
- Potential synergies of \$64 million already identified
 - \$29 million from R&D sub-teams
 - \$35 million from rationalization of low-rated projects (those rated terminated, hold, or pending) based on development reviews (\$16 million internal, \$19 million external)

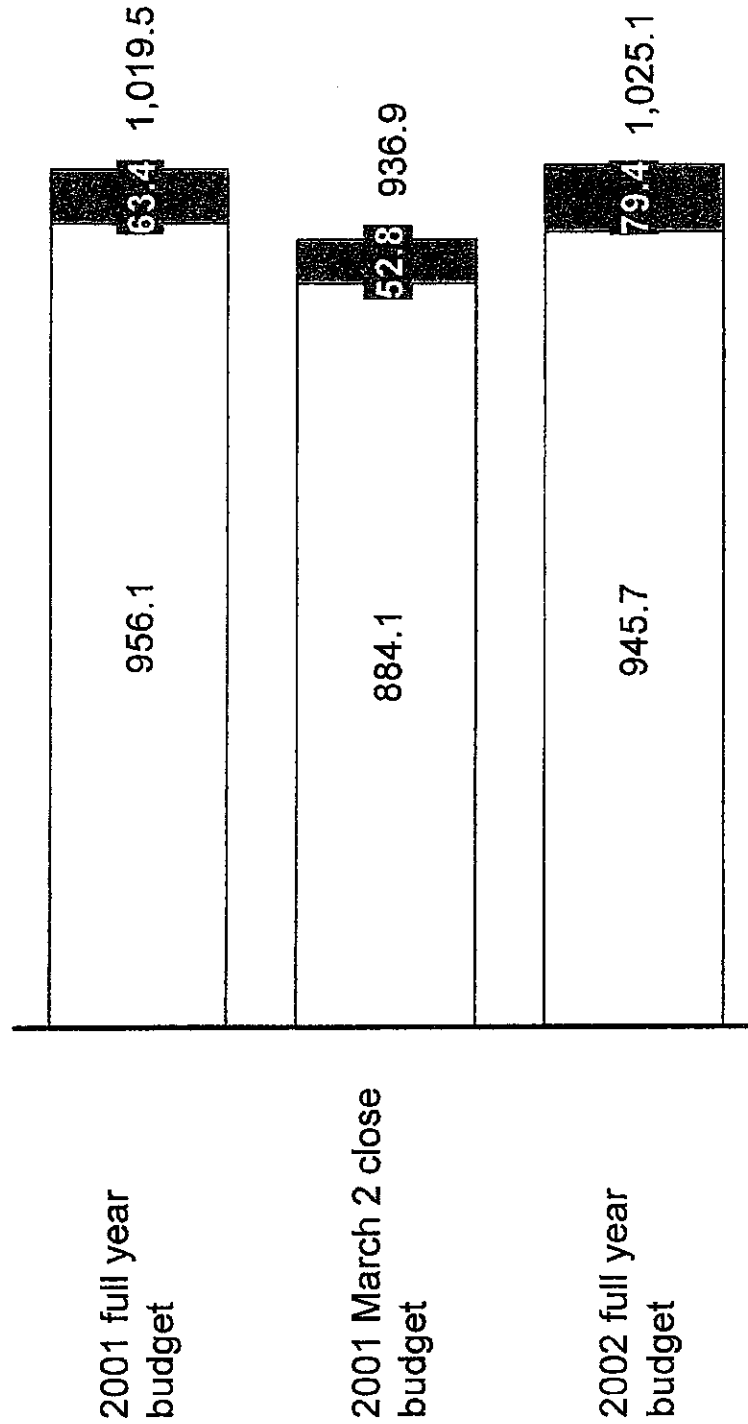
* Excludes affordability

CH-CH-228013-013jb/aARD

 Synergy
target

GPRD BUDGET AND SYNERGY TARGETS

\$ Millions



Source: GPRD Finance

CH-CH-228013-013jb/aaRD

SYNERGIES IDENTIFIED TO DATE

Percent; \$ millions

PRELIMINARY

	Percent of 2001 target achieved	Target 2001	Synergies		Cumulative headcount reductions	
			2001	2002	2001	2002
Regulatory affairs / QA	180	0.5	0.9	1.9	7	7
Data manage- ment / statistics	173	1.5	2.6	2.8	38	38
Medical affairs	120	1.5	1.8	3.4	26	26
CMC	105	10.0	10.5	21.6	207	184
IM&T	103	3.0	3.1	5.1	6	6
Phase I	100	1.0	1.0	2.5	7	8
Other (admin., etc)	100	2.0	2.0	3.3	0.2	0.2
Venture/global team management	100	4.5	4.5	8.9	93	93
Drug safety	70	3.0	2.1	3.6	15	15
Discovery	23	3.0	0.7	4.2	29	29
Total	97	30.0	29.2	57.3	430	408

Source: Synergy templates submitted by sub-teams

CH-CH-228013-013/b/aarD

PRELIMINARY**DESCRIPTION OF SYNERGIES**

Function	Key Initiatives
Data management/statistics	<ul style="list-style-type: none"> • Reduce head count globally, especially in Mt. Olive • Insource planned contracted work for Phase IV studies
Medical affairs	<ul style="list-style-type: none"> • Reduce global head count in marketed product development • Consolidate medical information personnel • Reduce health outcomes personnel in Ludwigshafen
CMC	<ul style="list-style-type: none"> • Close chemical plant in Ludwigshafen • Exit all CMC activities at Whiplany and Italy • Eliminate redundancies in PAR, PPD clinical packaging, and PPD QA • Increase formulation activities at Ludwigshafen
IM&T	<ul style="list-style-type: none"> • Cancel emerging dossier projects • Reduce U.S. R&D IT infrastructure costs
Phase I	<ul style="list-style-type: none"> • Increase utilization of Waukegan and Ludwigshafen Phase I units through right of first refusal for studies • Reduce head count globally
Other (Admin., etc.)	<ul style="list-style-type: none"> • Consolidate services purchased
Regulatory affairs/QA	<ul style="list-style-type: none"> • Reduce global head count and operating expenses
Venture/global team management	<ul style="list-style-type: none"> • Reduce head count in Mt. Olive and Canada • Optimize resources and internalize work
Drug safety	<ul style="list-style-type: none"> • Reduce external costs by shifting contracted work in Europe to Abbott Park • Consolidate radiochemistry at Abbott Park
Discovery	<ul style="list-style-type: none"> • Consolidate high throughput screening at Abbott Park

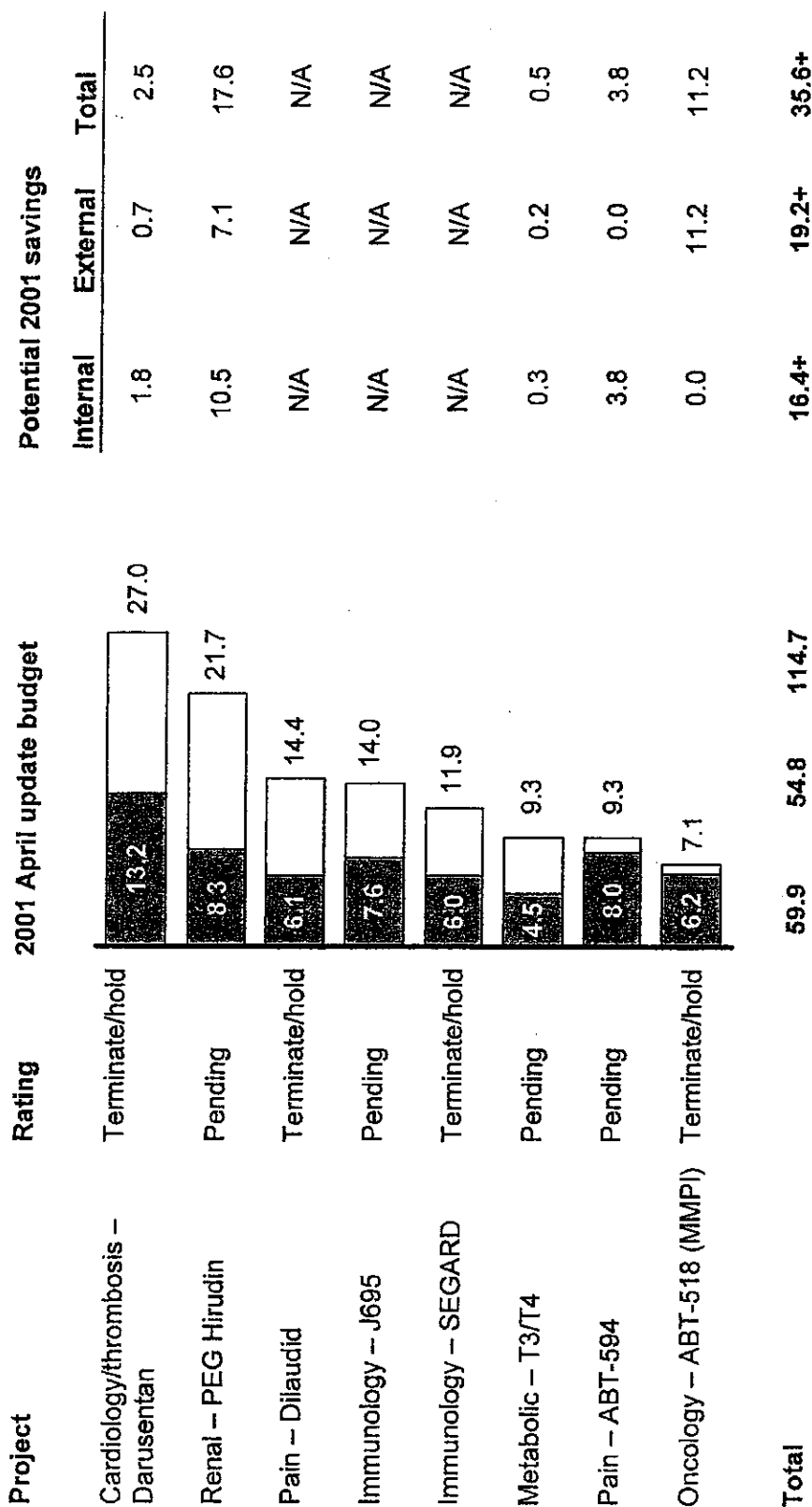
Source: Synergy templates submitted by sub-teams

CH-CH-228013-013/b/aRD

POTENTIAL SAVINGS FROM LOW-RANKED PROJECTS \$ Millions

PRELIMINARY

□ External
■ Internal



Note: Expected 2002 budget is \$179.3 million
Source: GPRD Finance; development review

CH-CH-228013-013p/aaRD

INITIAL PORTFOLIO PRIORITIZATION

C- Continue
P- Pending
T- Terminate

Project	Priority	Next steps	Responsibility	Timing
Anti-infectives ABT-492	C	<ul style="list-style-type: none"> Address safety issues (including QTc) with internal/ expert review Determine how many indications at launch (pay back) 	• J. Leonard	-
HSR-903	T	<ul style="list-style-type: none"> Consider trading with Daiichi Halt any new expenditure 	• J. Tyree	-
ABT-773	C	<ul style="list-style-type: none"> Assess side effects issues with expert review (QTc and liver tox.) Ensure all drug interactions are adequately covered Assess relative to Ketek 	<ul style="list-style-type: none"> • J. Leonard • J. Leonard • I. Loew-Friedrich 	-
Urology BSF 420627	P	<ul style="list-style-type: none"> Set up task force to address issues and bring back plan to senior management <ul style="list-style-type: none"> Reasons for failure of the SKB ETa/b antagonist Design short (~4 week) PoP trial for symptom relief Rationale for sustained release formulation Nature of the Schwarz Pharma relationship 	• J. Leonard	• By May
Hypothyroidism T3/T4	P	<ul style="list-style-type: none"> Assess most appropriate ratio Gain FDA feedback on study design Determine ex-US market attractiveness (price) 	• J. Leonard	• By May
Asthma Hokunalin tape	P	<ul style="list-style-type: none"> Conduct market research on acceptance by different patient segments Determine how to position against long acting beta agonists and combination inhalers Evaluate opportunity to gain complete access to the patch technology 	<ul style="list-style-type: none"> • A. Higgins/ E. Fiorentino • J. Tyree 	• May

CH-CH-228013-013b/aaRD

INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- Continue
P- Pending
T- Terminate

Project	Priority	Next steps	Responsibility	Timing
Oncology ABT-510	C	<ul style="list-style-type: none"> Pursue proof of concept Leverage TAP knowledge of angiogenesis product development (appropriate endpoints) 	<ul style="list-style-type: none"> Project team 	<ul style="list-style-type: none"> As planned
ABT-751	C	<ul style="list-style-type: none"> Pursue proof of concept Use echocardiogram to monitor potential cardiotoxicity Resolve potent drug manufacturing approach 	<ul style="list-style-type: none"> Project team CMC group Senior management 	<ul style="list-style-type: none"> As planned
ABT-518	Hold/T	<ul style="list-style-type: none"> Wait for May results from Pfizer (will save ~\$1mill) and re-evaluate Halt all further expenditure 	<ul style="list-style-type: none"> Senior management 	<ul style="list-style-type: none"> May
Rubitecan	P	<ul style="list-style-type: none"> Significant clinical rework required (funded by partner)- further in-depth review required Make a proceed decision when 2Q data available 	<ul style="list-style-type: none"> J. Leonard 	<ul style="list-style-type: none"> By May
Theragyn	P	<ul style="list-style-type: none"> Negative initial scientific perspective - further in-depth review required, e.g., <ul style="list-style-type: none"> Determine if there is a PoC to support claim Address GMP issues Determine best control to demonstrate efficacy Re-look at partnership contract 	<ul style="list-style-type: none"> J. Leonard 	<ul style="list-style-type: none"> By May
ABT-627	C	<ul style="list-style-type: none"> Seek alternative funding (e.g., NCI) before starting major trial If move ahead <ul style="list-style-type: none"> Determine how to ensure NDA filing in 2004 Get FDA input since survival not primary endpoint Harmonize US and EU study design and inputs Consider partnership (e.g., BI or established oncology player) 	<ul style="list-style-type: none"> J. Tyree J. Leonard, P. Nisen 	<ul style="list-style-type: none"> By May ASAP
			<ul style="list-style-type: none"> J. Tyree 	<ul style="list-style-type: none"> By May

CH-CH-228013-013/b/aarD

INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- Continue
P- Pending
T- Terminate

Project	Priority	Next steps	Responsibility	Timing
Cardiology/ thrombolysis Darusentan (LU 135252)	Hold/T	<ul style="list-style-type: none"> Continue currently budgeted funding for next 6 months Do not start any new trials (e.g., hypertension planned for May) Consider out-license or swap 	<ul style="list-style-type: none"> Project team 	<ul style="list-style-type: none"> Ongoing
LU 208075	Hold/T	<ul style="list-style-type: none"> Continue currently budgeted funding for next six months Look at Myogen deal Out-license or swap 	<ul style="list-style-type: none"> J. Tyree 	<ul style="list-style-type: none"> ASAP
Levosimendan	C	<ul style="list-style-type: none"> Conduct detailed expert panel review for trial design 	<ul style="list-style-type: none"> Project team 	<ul style="list-style-type: none"> ongoing
PEG-hirudin	P	<ul style="list-style-type: none"> Set up expert panel for commercial assessment (is diabetes an option?) 	<ul style="list-style-type: none"> J. Tyree 	<ul style="list-style-type: none"> ASAP
Ancrod	T	<ul style="list-style-type: none"> Identify out-licensing opportunities 	<ul style="list-style-type: none"> J. Leonard 	<ul style="list-style-type: none"> May
Urokinase	P	<ul style="list-style-type: none"> Market research required on open cath Match versus tPA in dose-ranging studies to determine efficacy 	<ul style="list-style-type: none"> E. Ogunro 	<ul style="list-style-type: none"> By May
Pro-urokinase	C	<ul style="list-style-type: none"> Identify opportunities to speed up program 	<ul style="list-style-type: none"> J. Tyree 	<ul style="list-style-type: none"> TBD
Clivarine	C	<ul style="list-style-type: none"> Assessment by HPD (review previous evaluation and new trial data) Understand finished product manufacturing cost 	<ul style="list-style-type: none"> Project team 	<ul style="list-style-type: none"> TBD
Rythmol SR	C	<ul style="list-style-type: none"> Continue filing Verify if package is likely approvable Assess commercial attractiveness in a generic market 	<ul style="list-style-type: none"> E. Ogunro B. Dempsey Project team 	<ul style="list-style-type: none"> By May Ongoing

CH-CF-228013-013/b/aarD

INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- Continue
P- Pending
T- Terminate

Project	Priority	Next steps	Responsibility	Timing
Neuroscience ABT 594	P	<ul style="list-style-type: none"> • Await results from ongoing PII trial – probable T • Project team to develop decision criteria for go/no go 	<ul style="list-style-type: none"> • Senior management 	<ul style="list-style-type: none"> • June/ July
ABT 963	C	<ul style="list-style-type: none"> • Identify a co-development/co-promotion partner (TAP high on list) • Evaluate benefits of the long half life in pain and cancer (including additional physician market research) • Explore cancer prophylaxis and Alzheimer's Indications 	<ul style="list-style-type: none"> • J. Tyree • Project team 	<ul style="list-style-type: none"> • TBD
BSF 201640	P	<ul style="list-style-type: none"> • Complete review of all schizophrenia NCEs with expert panel • Complete staffing of internal project team, but halt further expenditure beyond looking at hepatic tox. and QTc • Understand Novartis contract and level of interest 	<ul style="list-style-type: none"> • I. Loew-Freidrich • Project team • J. Tyree 	<ul style="list-style-type: none"> • By May
BSF 190555	P	<ul style="list-style-type: none"> • Complete review as above • Halt further expenditure pending outcome 	<ul style="list-style-type: none"> • I. Loew-Freidrich 	<ul style="list-style-type: none"> • As above
BSF 74398	C (no cost)	<ul style="list-style-type: none"> • Allow DevCo to continue development • Re-look at relationship with DevCo 	<ul style="list-style-type: none"> • Project team • J. Tyree 	<ul style="list-style-type: none"> • By May
Diluadid Oros	Hold/T	<ul style="list-style-type: none"> • Return to ALZA or out-license to other interested partner 	<ul style="list-style-type: none"> • J. Tyree 	<ul style="list-style-type: none"> • TBD
Hydrocodone	C	<ul style="list-style-type: none"> • Assess regulatory pathway • Understand DEA impact on manufacturing 	<ul style="list-style-type: none"> • Project team 	<ul style="list-style-type: none"> • By May
Bimoclomol (ABT 822)	P	<ul style="list-style-type: none"> • Await data from ongoing trial in April before deciding whether to continue - probable T • Halt further expenditure pending outcome 	<ul style="list-style-type: none"> • Senior management 	<ul style="list-style-type: none"> • April

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INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)C- Continue
P- Pending
T- Terminate

Project	Priority	Next steps	Responsibility	Timing
Gastro-enterology Ganaton	P	<ul style="list-style-type: none"> • Conduct U.S. commercial assessment with TAP • Assess how to position in Europe versus generics and implications for comparative trial • Develop model to assess spend at different termination points 	• E. Fiorentino	• By June
TU-199	T	<ul style="list-style-type: none"> • Terminate outside Japan 	• Bob Funck	• By May
AU-224	C	<ul style="list-style-type: none"> • Develop and pursue a small PoC trial in humans ASAP (consider niche indication first and leverage Marlene's expertise) • Conduct market research on IBS versus constipation (including pricing) 	• Project team • Project team	• Immediate • ASAP
Immunology D2E7	C	<ul style="list-style-type: none"> • Conduct intensive product review <ul style="list-style-type: none"> - 2 day meeting with J. Leonard's group (already in process) - ½ day session with senior management group • Important actions include <ul style="list-style-type: none"> - Approach FDA for fast track and compassionate use - Develop strategy for DIMARD claim in first submission - Assess need for Enbrel assay to detect HAHAs - Assess delivery device options - Evaluate additional indications (e.g., psoriasis, Crohns, heart failure) and pediatric program - Profile Celltech product - Assess impact of additional IV program on reimbursement • Develop list of potential marketing partners for quids 	• J. Leonard • Various	• By May • By May
			• J. Tyree	

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INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)C- Continue
P- Pending
T- Terminate

Project	Priority	Next steps	Responsibility	Timing
Immunology (continued) Segard	Hold	<ul style="list-style-type: none"> • Continue filing in EU and Canada • Put on hold in US – consider creating a small team in the US to analyse data, propose smaller P/I study • Research pricing, marketing and Phase IV plans in Europe • Look at TNF-alpha levels retrospectively to see stratification with IL-6 • Assess manufacturing strategy • Identify potential out-licensing opportunities (Genentech) 	<ul style="list-style-type: none"> • Project team • J. Leonard 	<ul style="list-style-type: none"> • Ongoing
J695	P	<ul style="list-style-type: none"> • Decide on most attractive indications from Abbott and partner perspective • Discuss with partner ways to share the various indications and potential for TNF-alpha combinations • Add commercial person to the project team by this week 	<ul style="list-style-type: none"> • J. Tyree • E. Fiorentino • J. Tyree • Ongoing 	<ul style="list-style-type: none"> • ASAP

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INITIAL PORTFOLIO PRIORITIZATION (CONTINUED)

C- Continue
P- Pending
T- Terminate

Project	Priority	Next steps	Responsibility	Timing
PIV programs				
Clarithromycin	C	• None identified	-	-
Omnicef	C	• None identified	-	-
Kaletra	C	• None identified	-	-
Norvir	C	• None identified	-	-
Meridia	Hold	<ul style="list-style-type: none"> • Conduct commercial assessment for CNS and depression (P&L) • Assess combination therapy with fibrates • Assess outcomes trial design to meet preferred commercial profile; determine payback 	<ul style="list-style-type: none"> • B. Dempsey, J. Arnott, E. Fiorentino • Project team 	<ul style="list-style-type: none"> • ASAP
Uprima	C	• Ensure no redundant trials with TAP in Europe	• Project team	• Ongoing
Trandolapril patch	T	• Halt all activities	• Project team	• Immediate
Trandolapril "Invest" clinical program	P	• Review trial in more detail (reduce complexity and risk)	• E. Fiorentino	• By May
Other trandolapril trials	C	• Continue "Create", "Peace" and "Benedict" trial programs	• Project team	• Ongoing
Fenofibrate	C	• Develop co-formulation ideas with Meridia and statins (including assessment of sales and costs)	• Project team	-
Depakote	C	• None identified	-	-
Gengraf	C	• None identified	-	-

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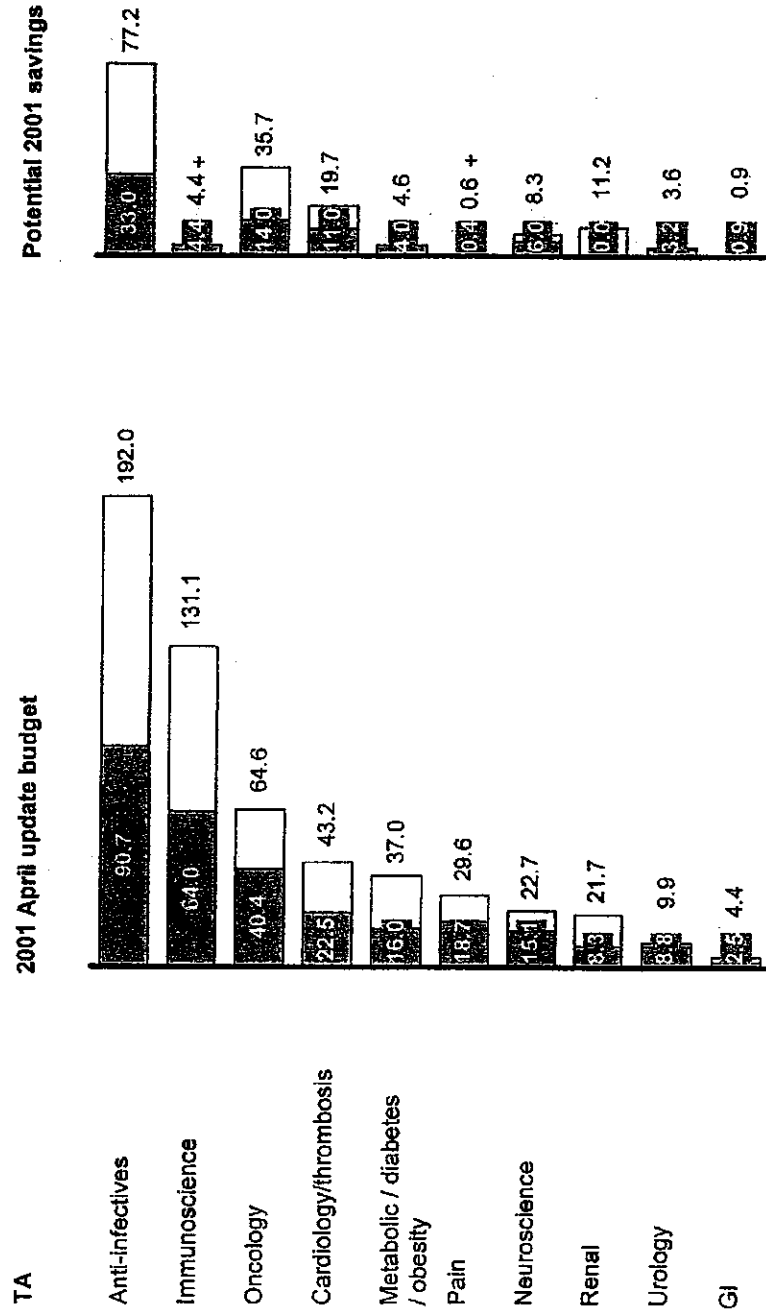
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POTENTIAL DEVELOPMENT PROGRAM SAVINGS IN 2001 IF TA TERMINATED

\$ Millions

External
Internal

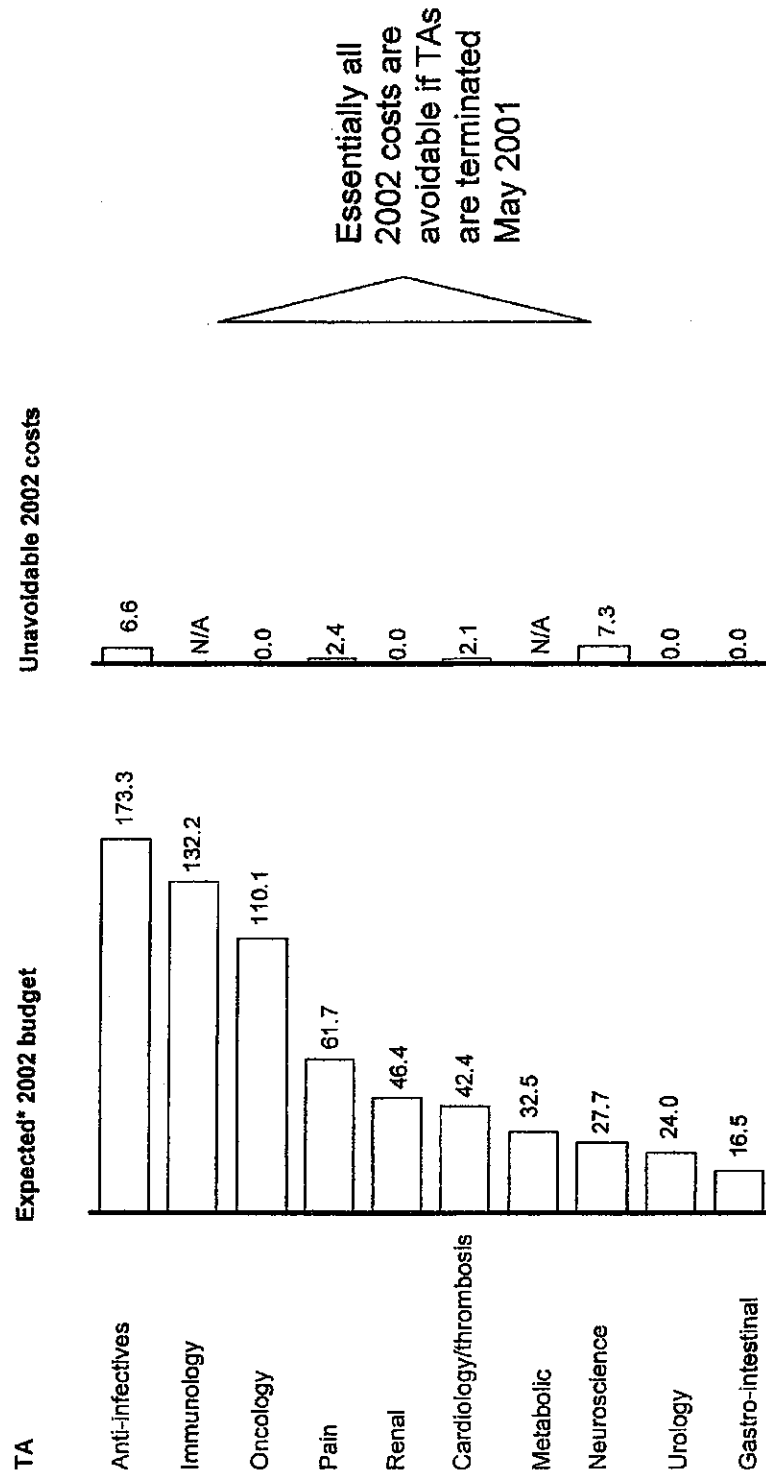


Note: Because of incomplete survey responses assumes limited savings from sibutramine, B201640, T4/T3, Synthroid, Vicoprofen, Dilaudid, Hydrocodone, PEG-Hirudin, and BSF 420627

Source: GPRD Finance

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POTENTIAL DEVELOPMENT PROGRAM SAVINGS IN 2002 IF TA TERMINATED **\$ Millions**



* Risk adjusted

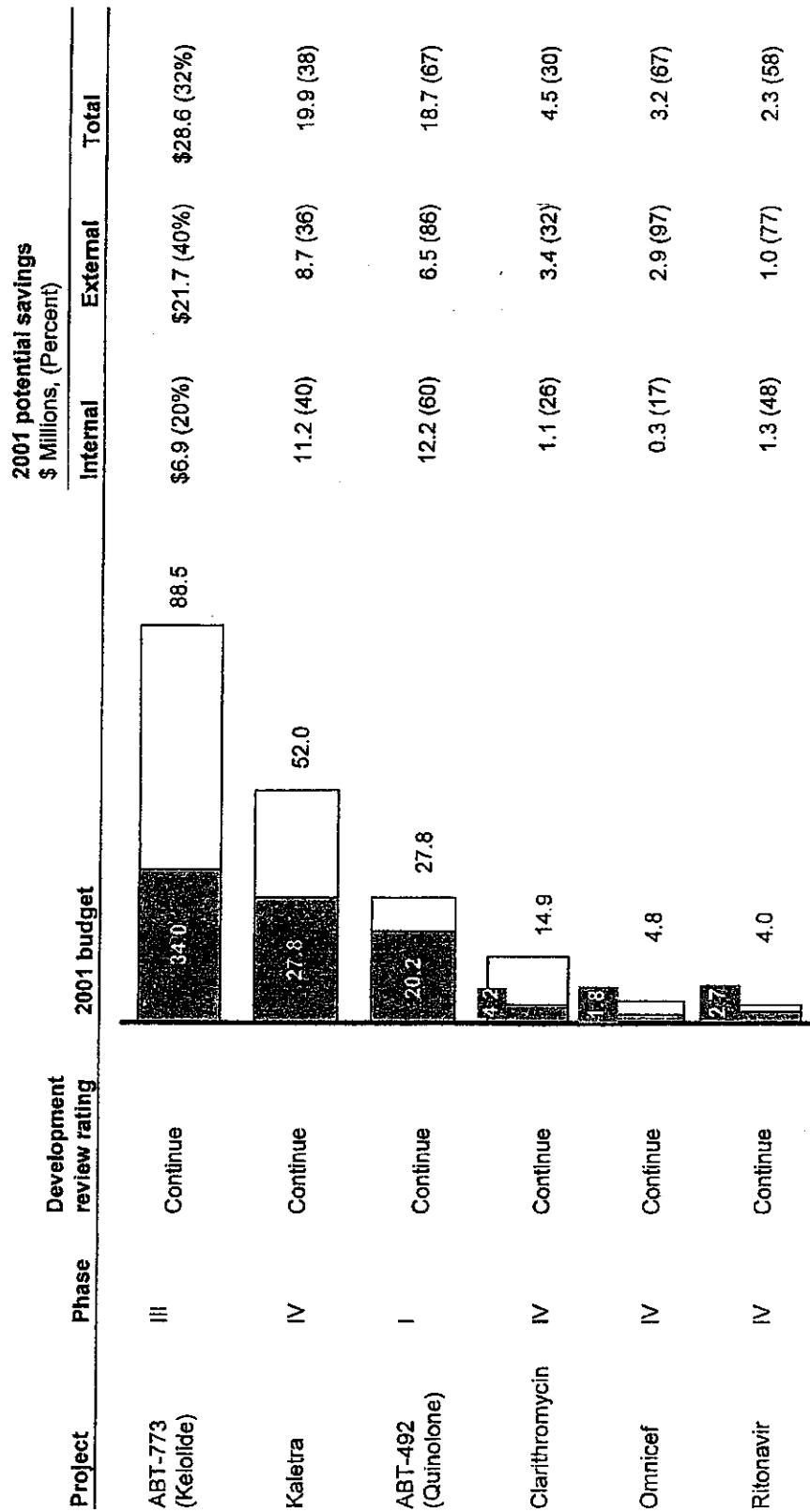
Note: N/A means not available

Source: GPRD Finance

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POTENTIAL SAVINGS – ANTI-INFECTIVES \$ Millions

□ External
■ Internal



Source: GPRD Finance

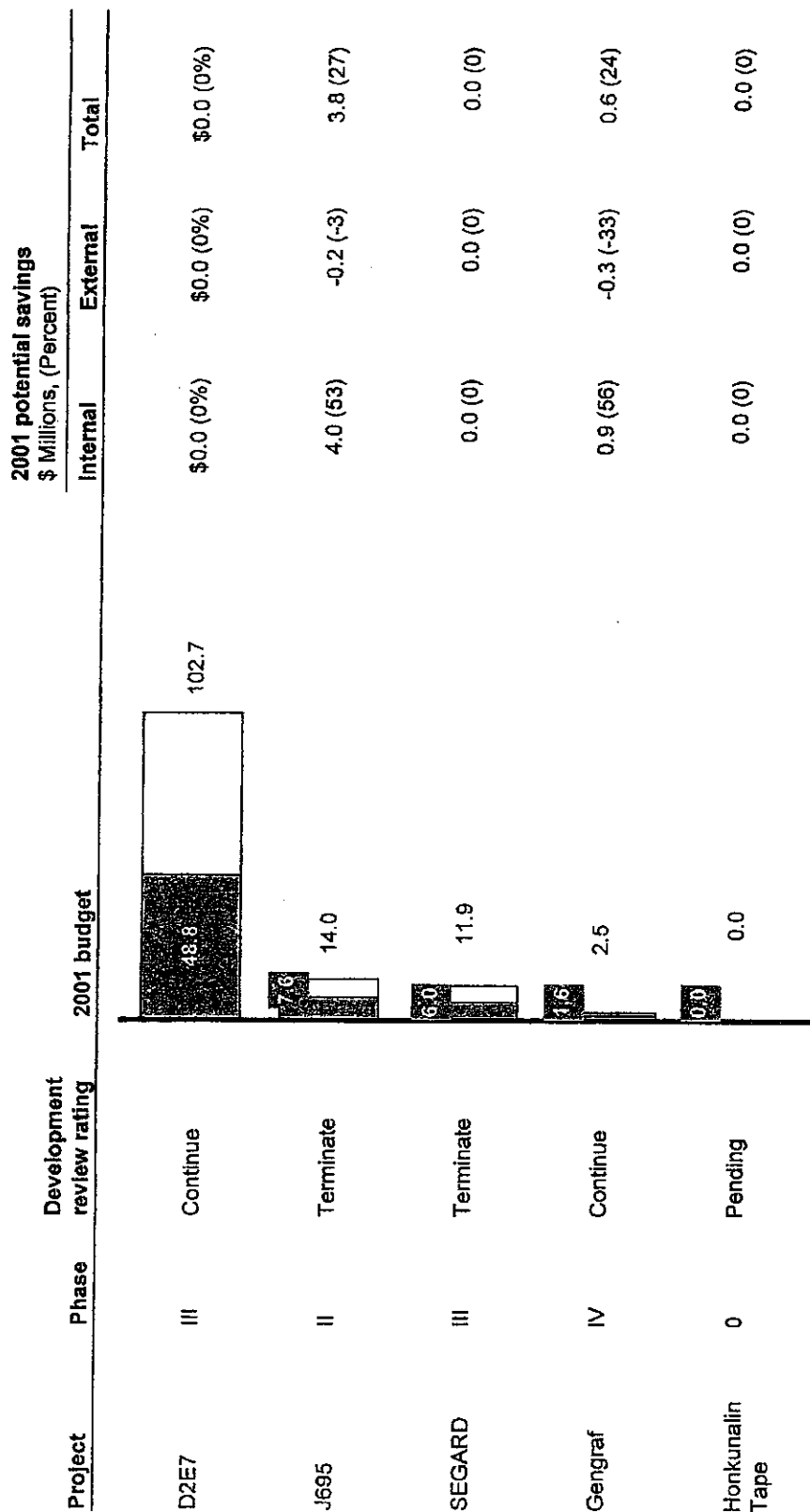
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POTENTIAL SAVINGS – IMMUNOLOGY

\$ Millions

External
Internal



Source: GPRD Finance

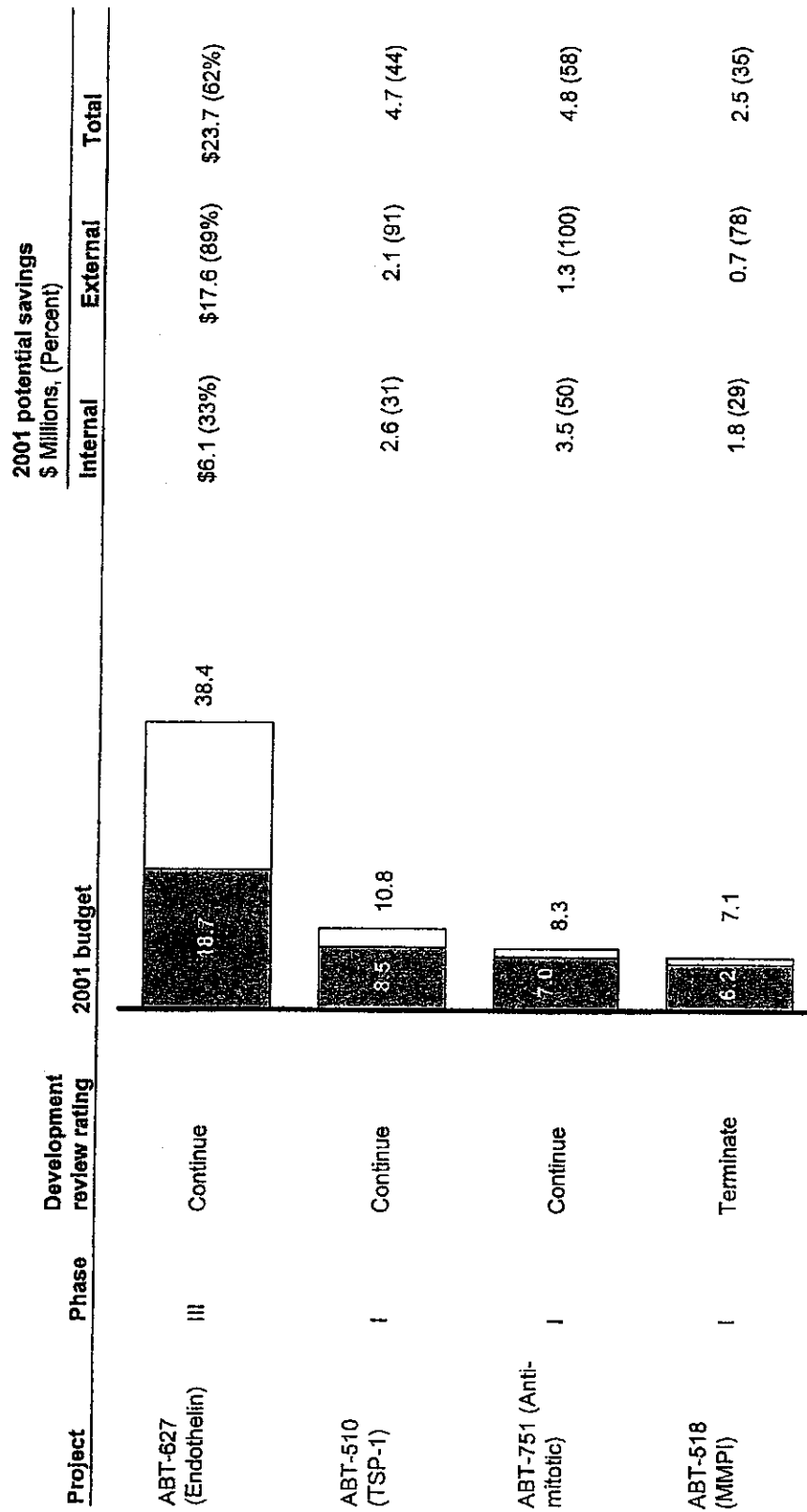
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POTENTIAL SAVINGS – ONCOLOGY

\$ Millions

External
Internal



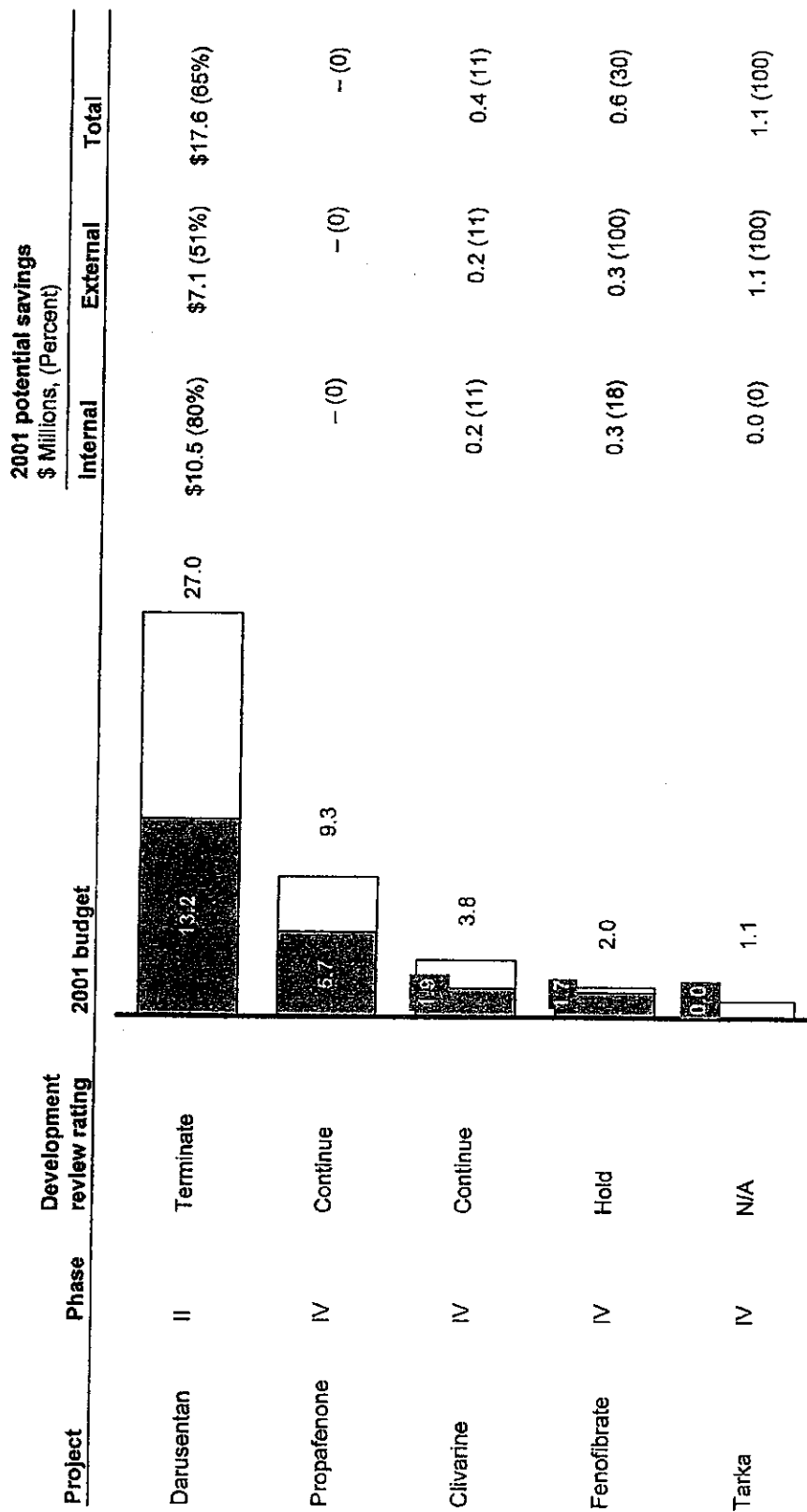
Source: GPRD Finance

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POTENTIAL SAVINGS -- CARDIOLOGY/THROMBOSIS \$ Millions

□ External
■ Internal



Source: GPRD Finance

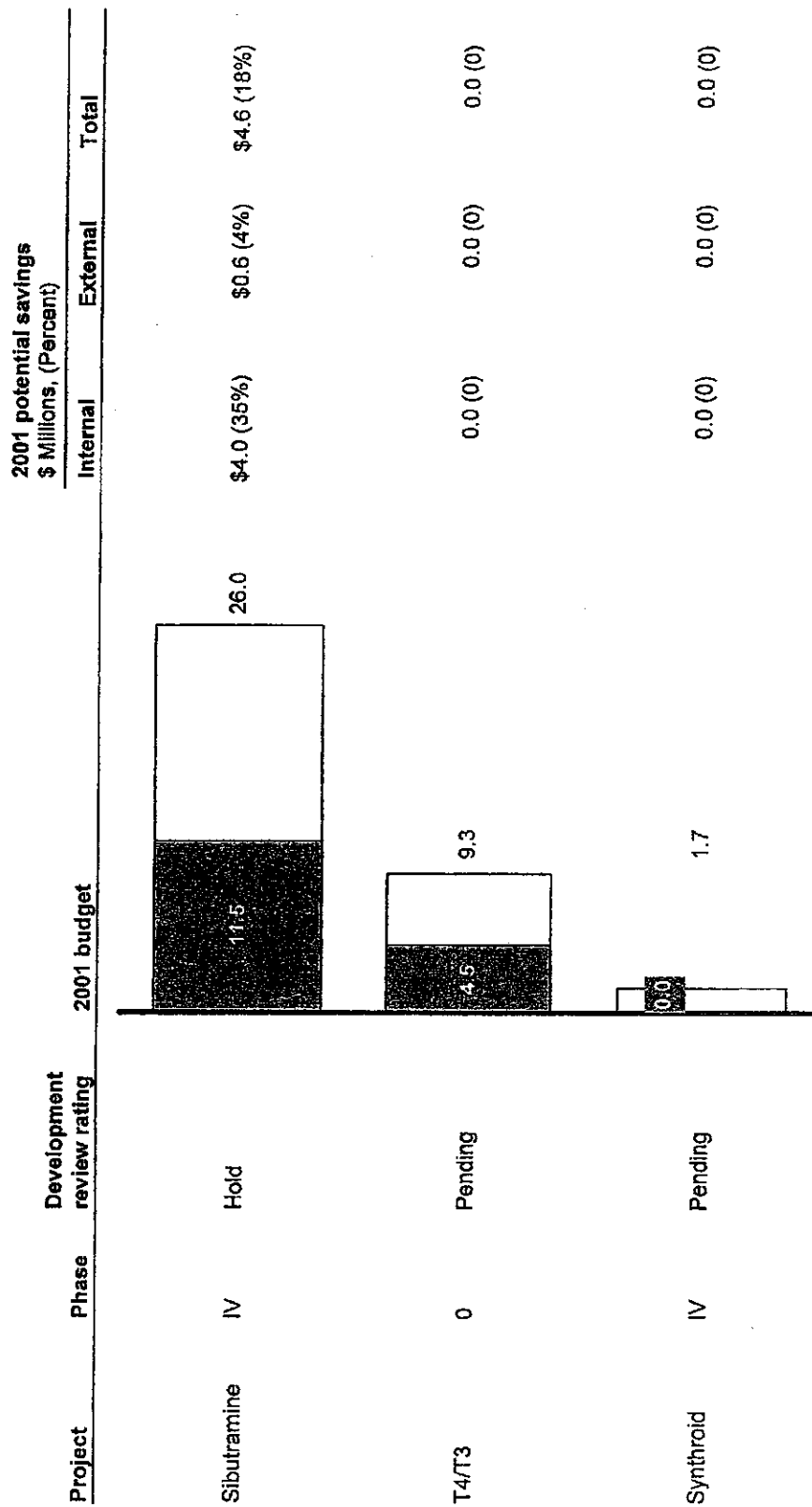
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POTENTIAL SAVINGS – METABOLIC / DIABETES / OBESITY

\$ Millions

External
Internal



Source: GPRD Finance

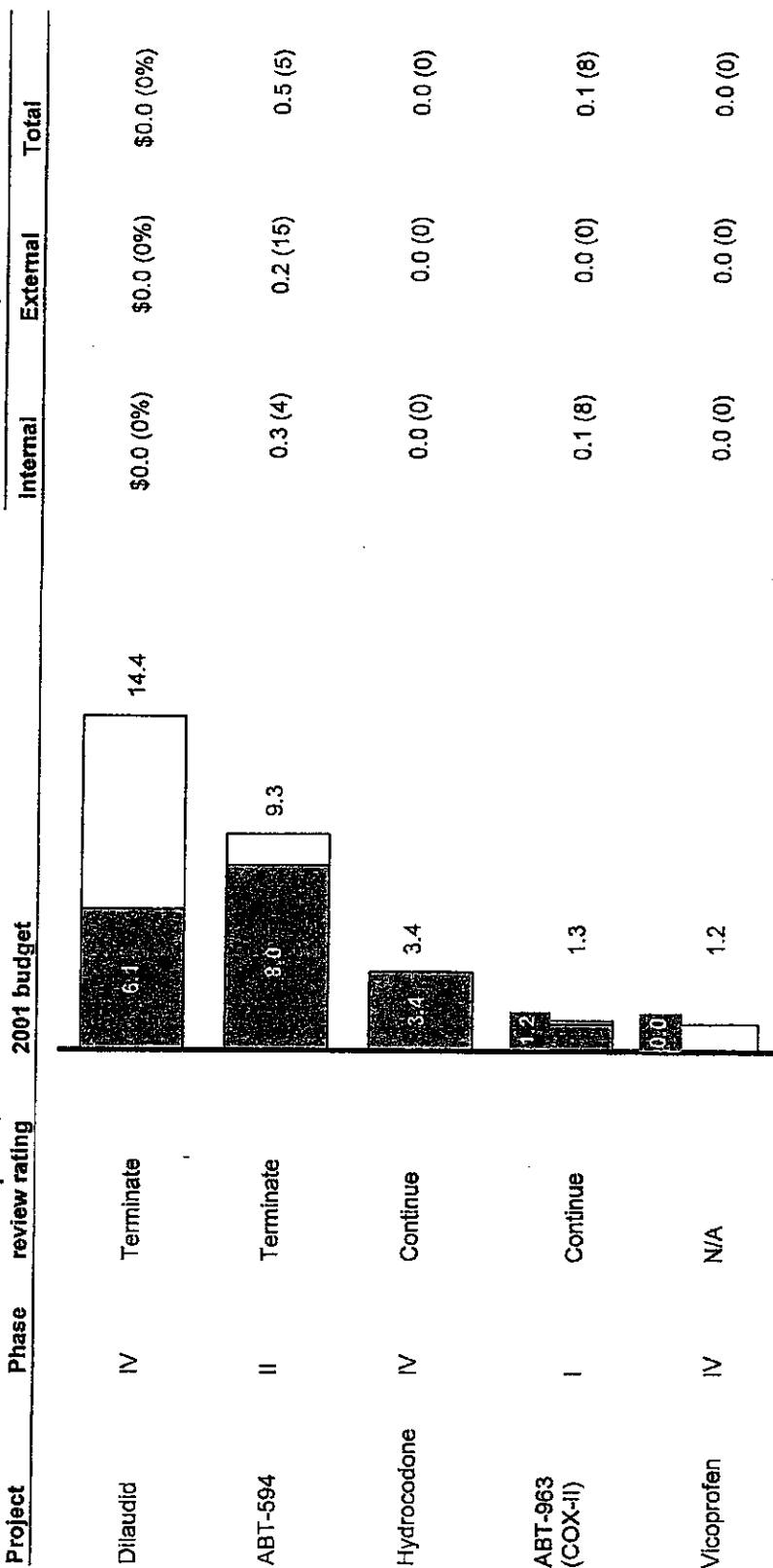
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POTENTIAL SAVINGS – PAIN \$ Millions

□ External
■ Internal

2001 potential savings
\$ Millions, (Percent)



Source: GPRD Finance

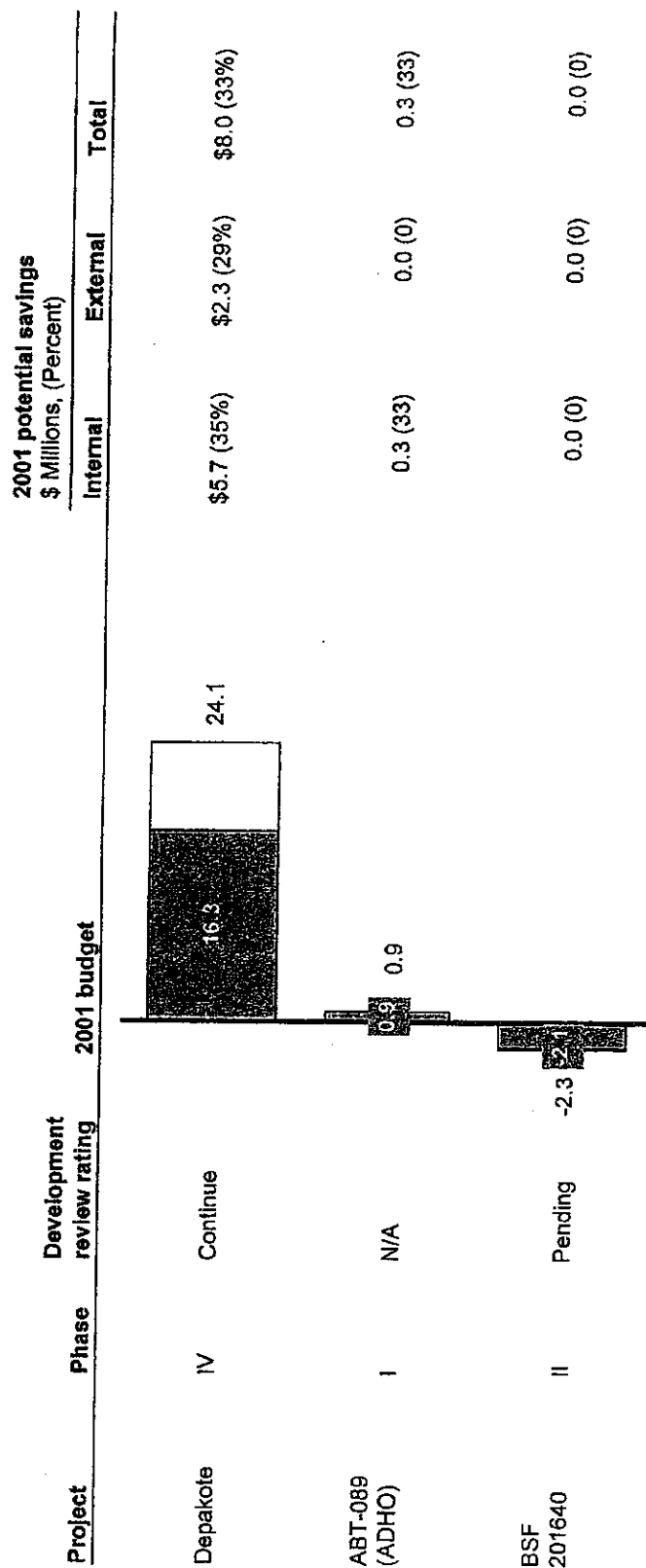
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POTENTIAL SAVINGS – NEUROSCIENCE

\$ Millions

External
Internal



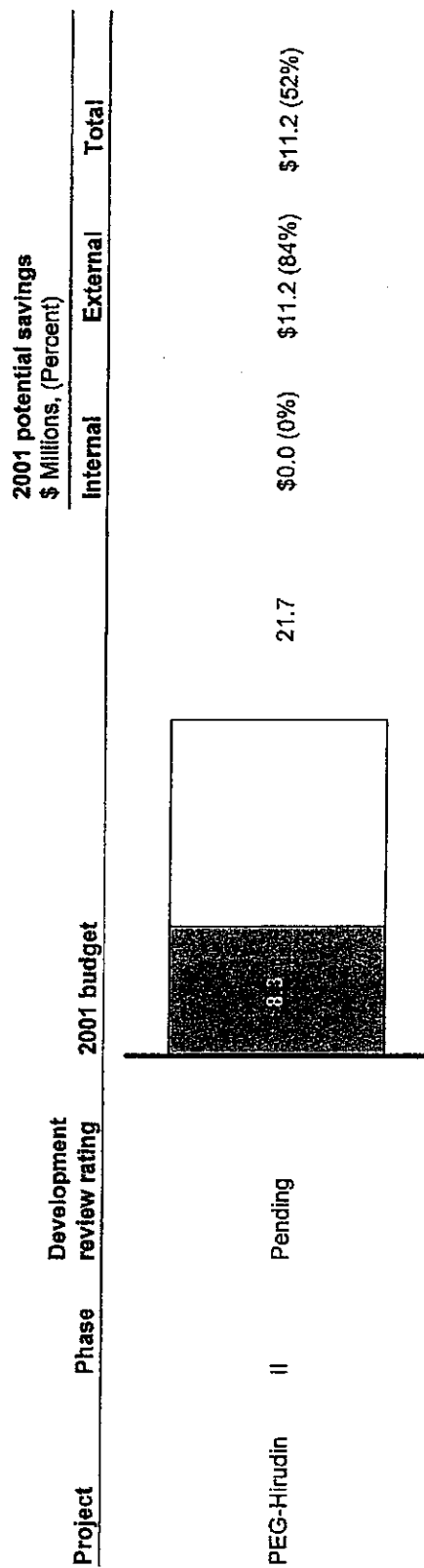
Source: GPRD Finance

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POTENTIAL SAVINGS – RENAL \$ Millions

☐ External
☒ Internal

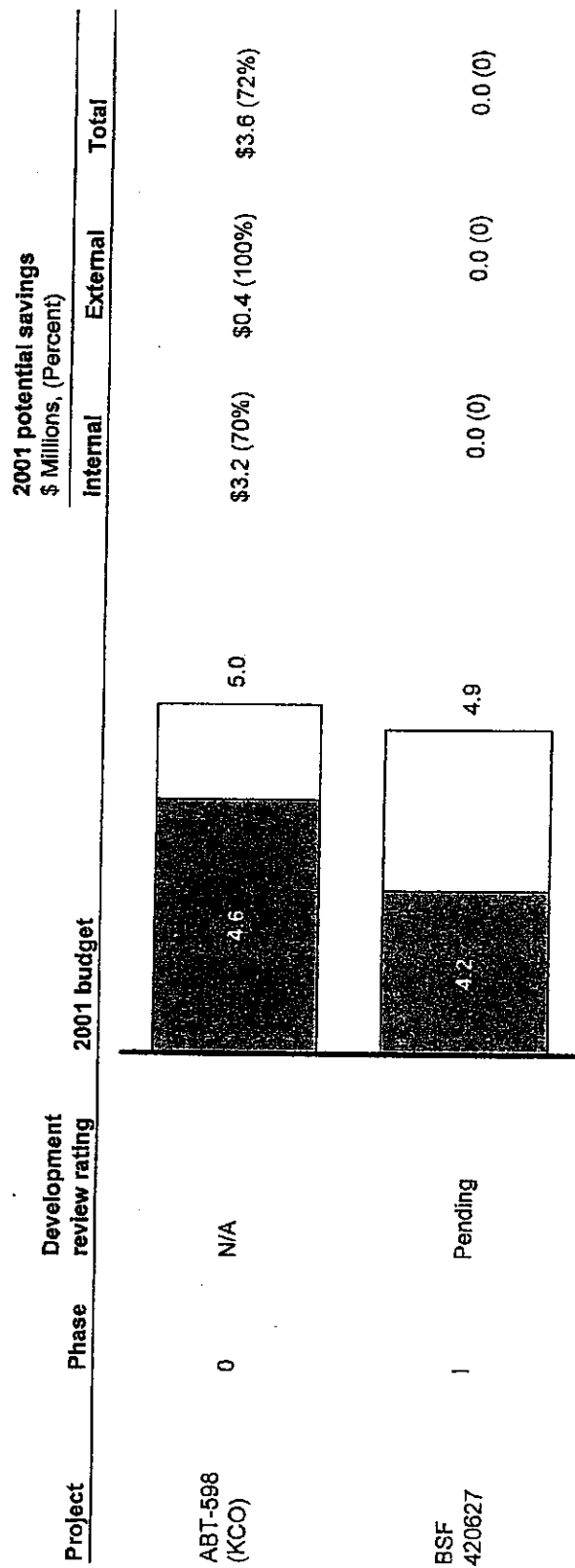


Source: GPRD Finance

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POTENTIAL SAVINGS – UROLOGY \$ Millions

□ External
■ Internal



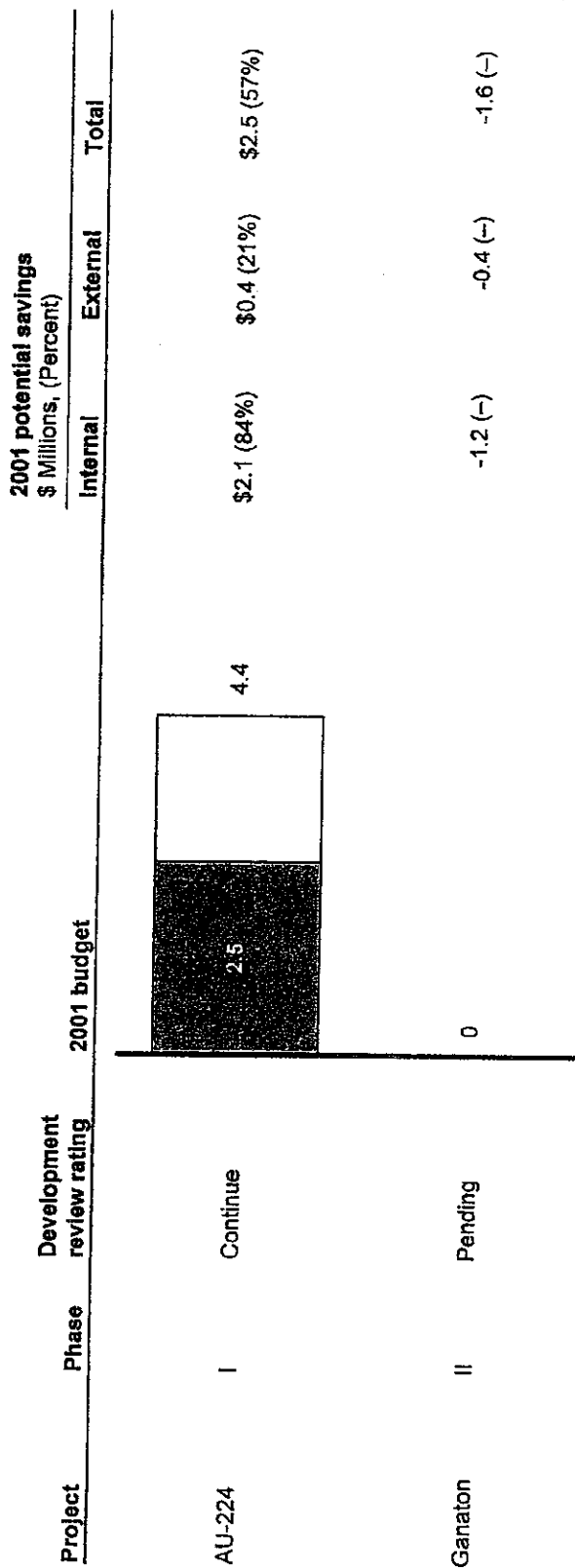
Source: GPRD Finance

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POTENTIAL SAVINGS – GI \$ Millions

☐ External
☒ Internal



Source: GPRD Finance

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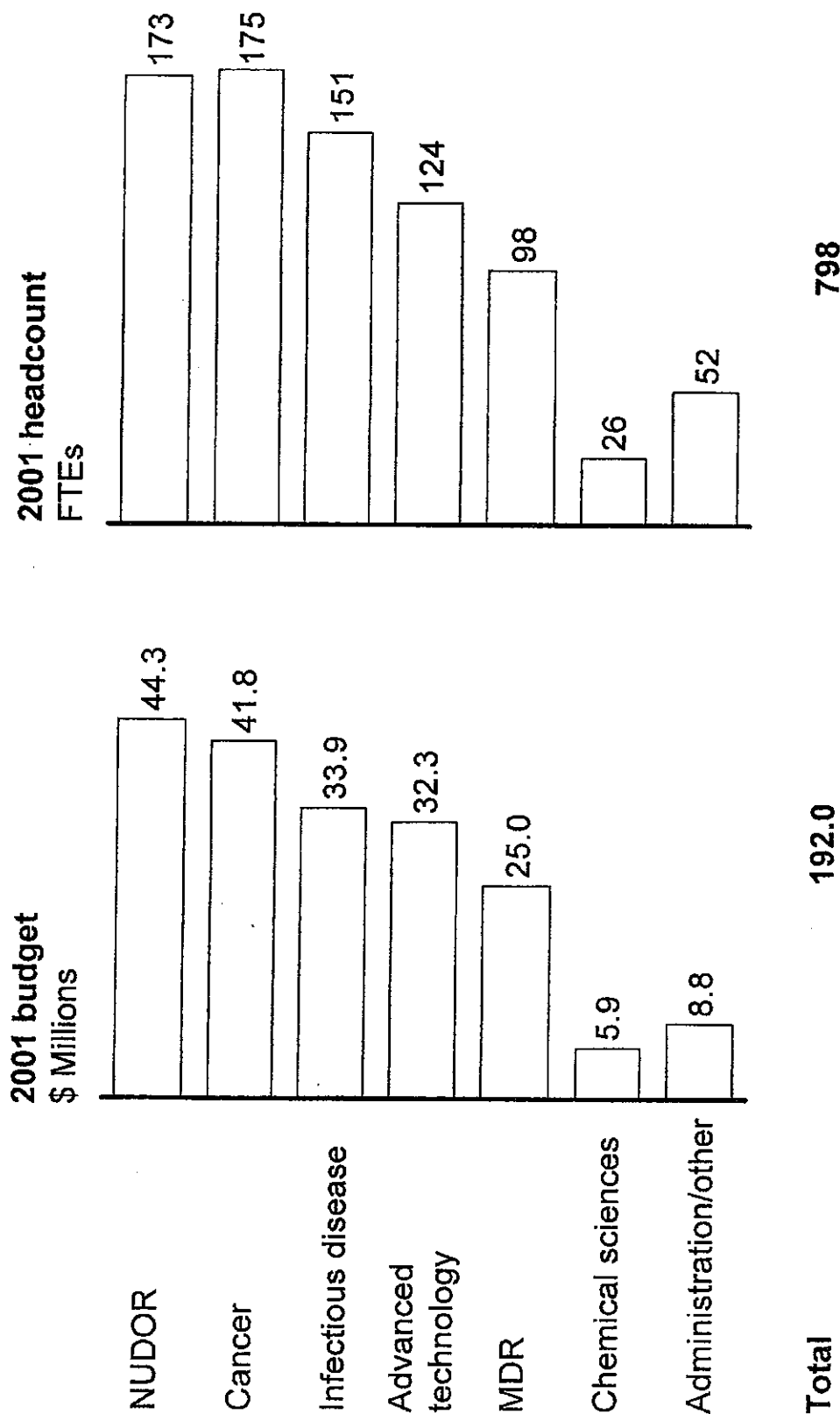
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APRIL UPDATE

ABBOTT PARK DISCOVERY – OVERVIEW

\$ Millions; FTE

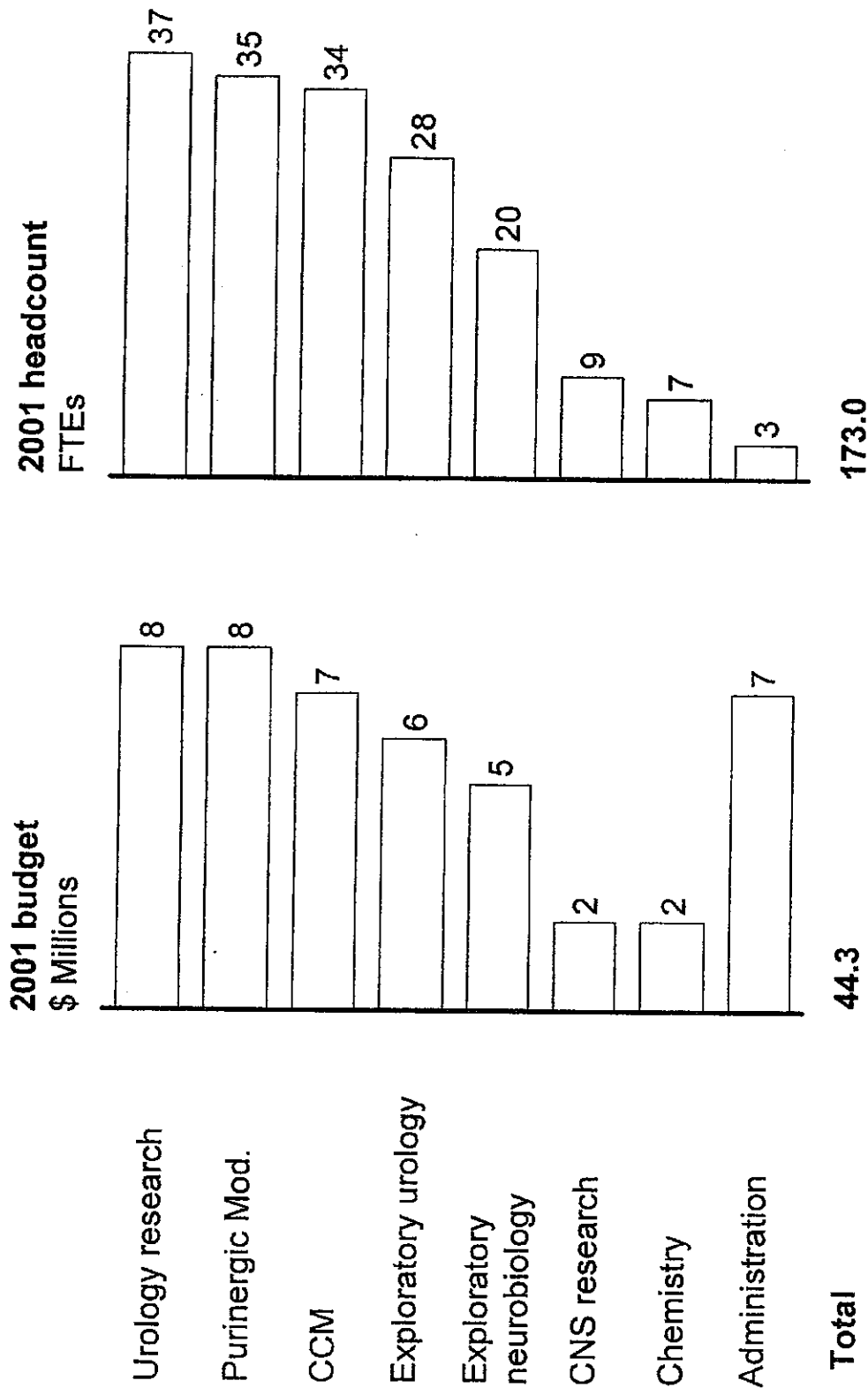


Source: GPRD Finance

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PRELIMINARY

ABBOTT PARK DISCOVERY – NUDOR \$ Millions; FTE



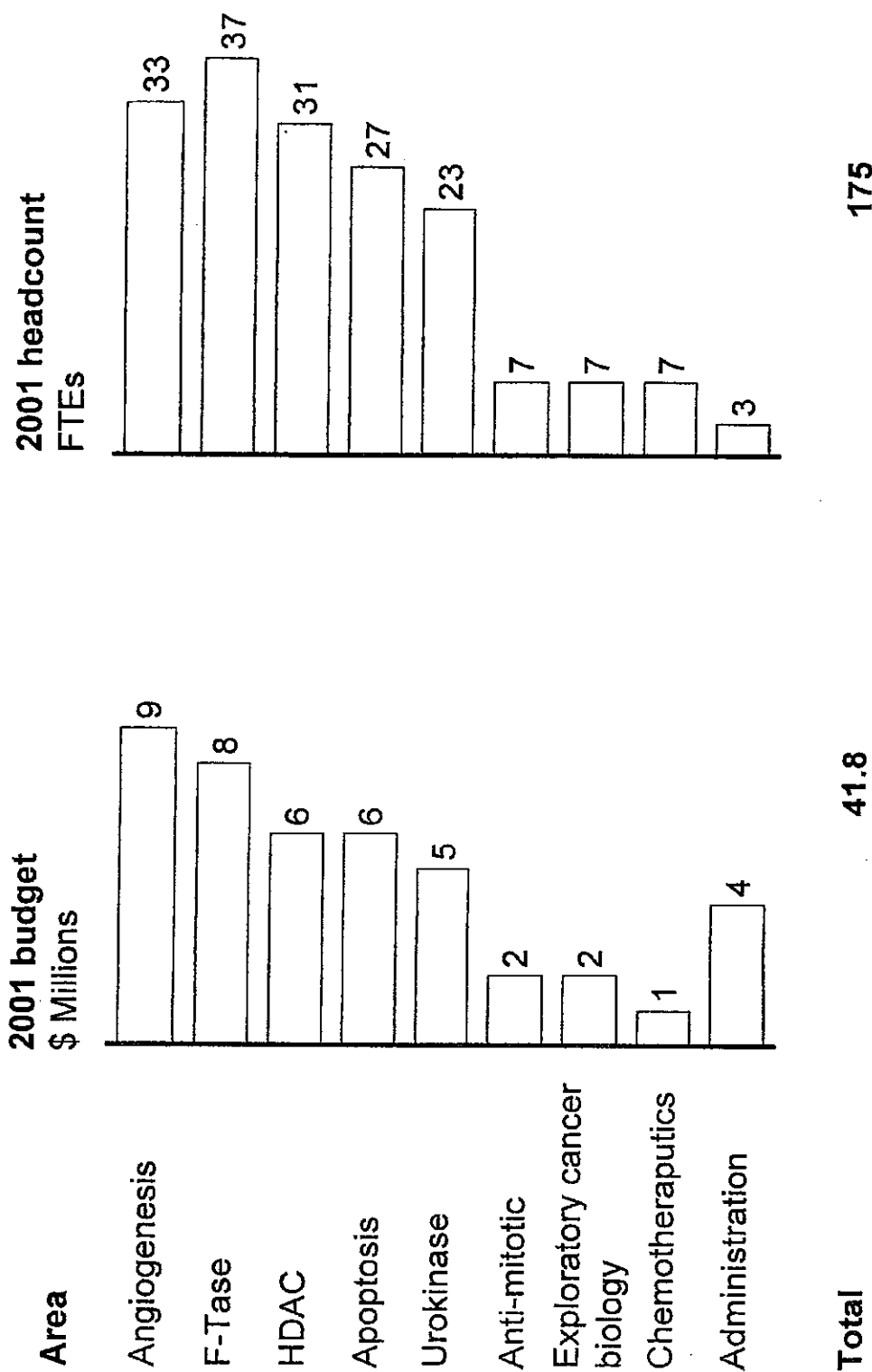
Source: GPRD Finance

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APRIL UPDATE**ABBOTT PARK DISCOVERY – CANCER**

\$ Millions; FTE



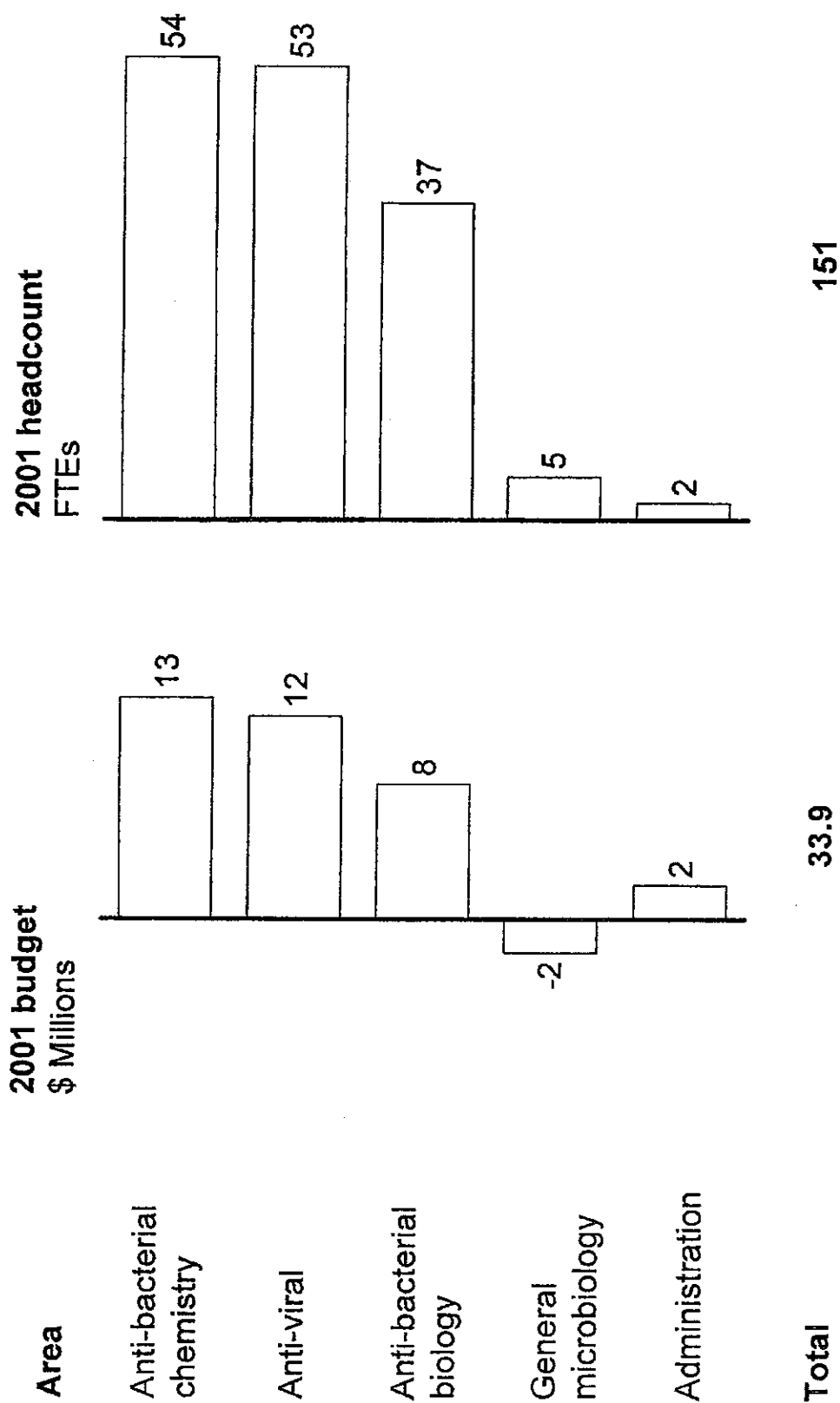
Source: GPRD Finance

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APRIL UPDATE**ABBOTT PARK DISCOVERY – INFECTIOUS DISEASE**

\$ Millions; FTE



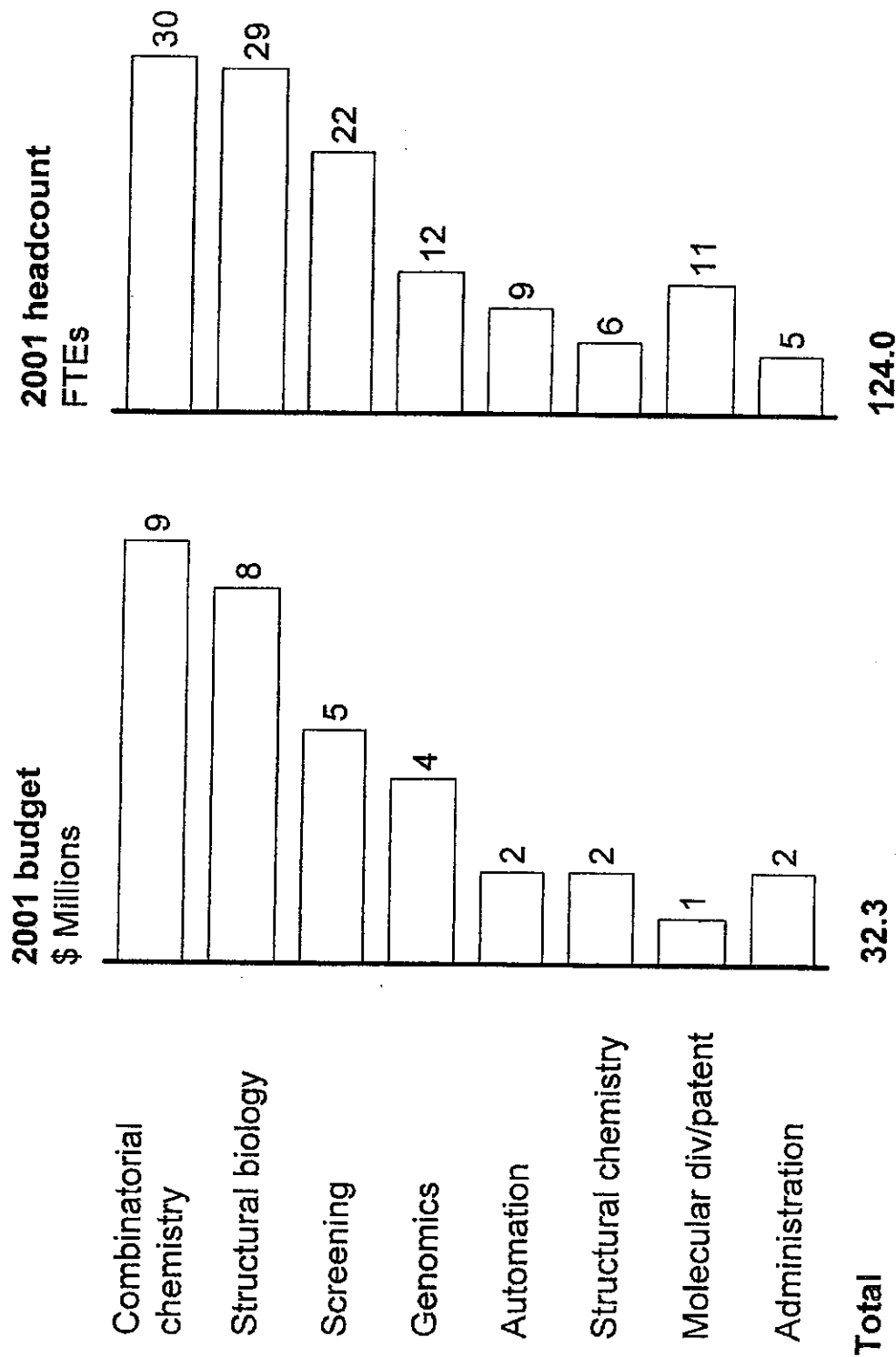
Source: GPRD Finance

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PRELIMINARY

ABBOTT PARK DISCOVERY – ADVANCED TECHNOLOGY \$ Millions; FTE



Source: GPRD Finance

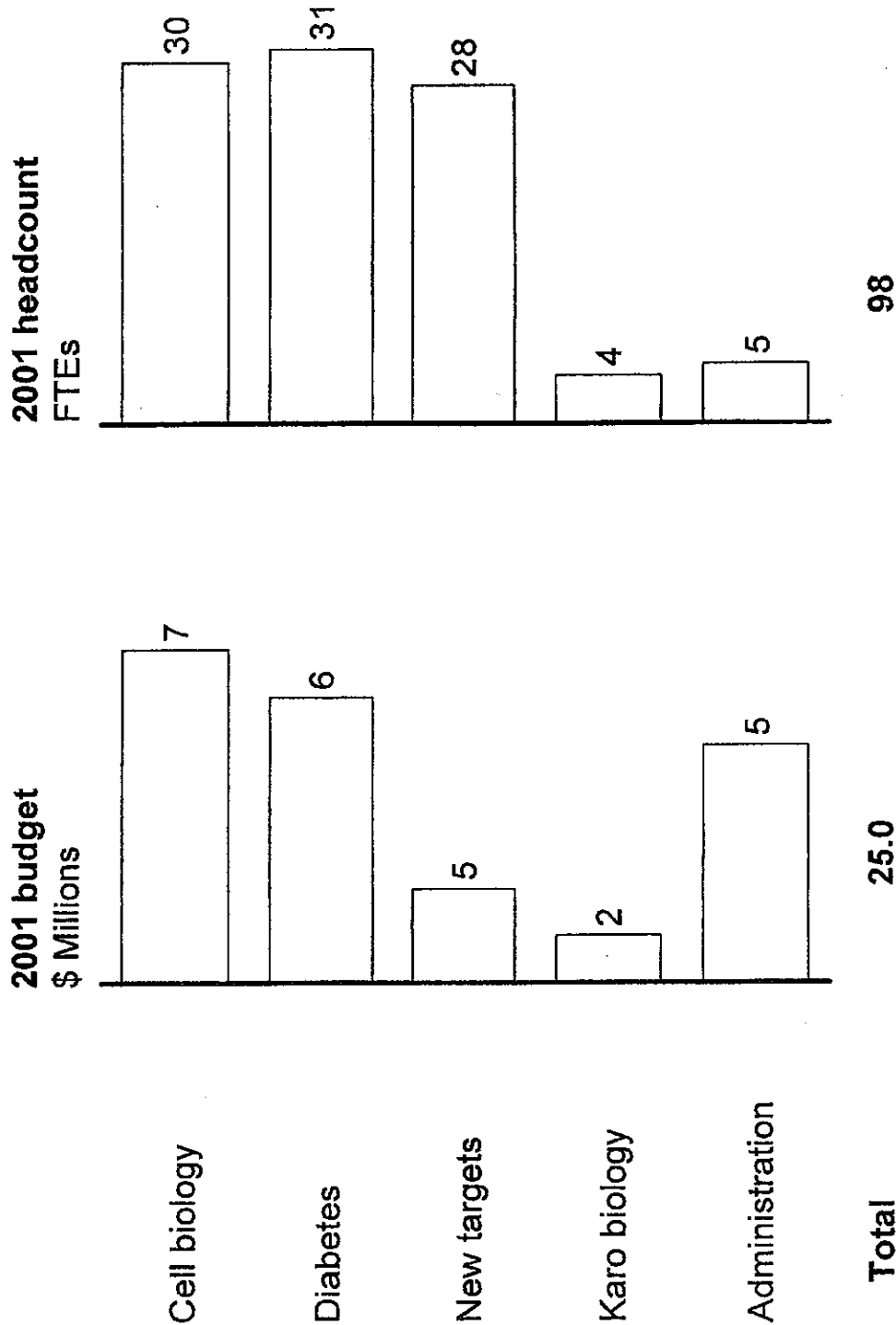
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PRELIMINARY

ABBOTT PARK DISCOVERY – MDR

\$ Millions; FTE



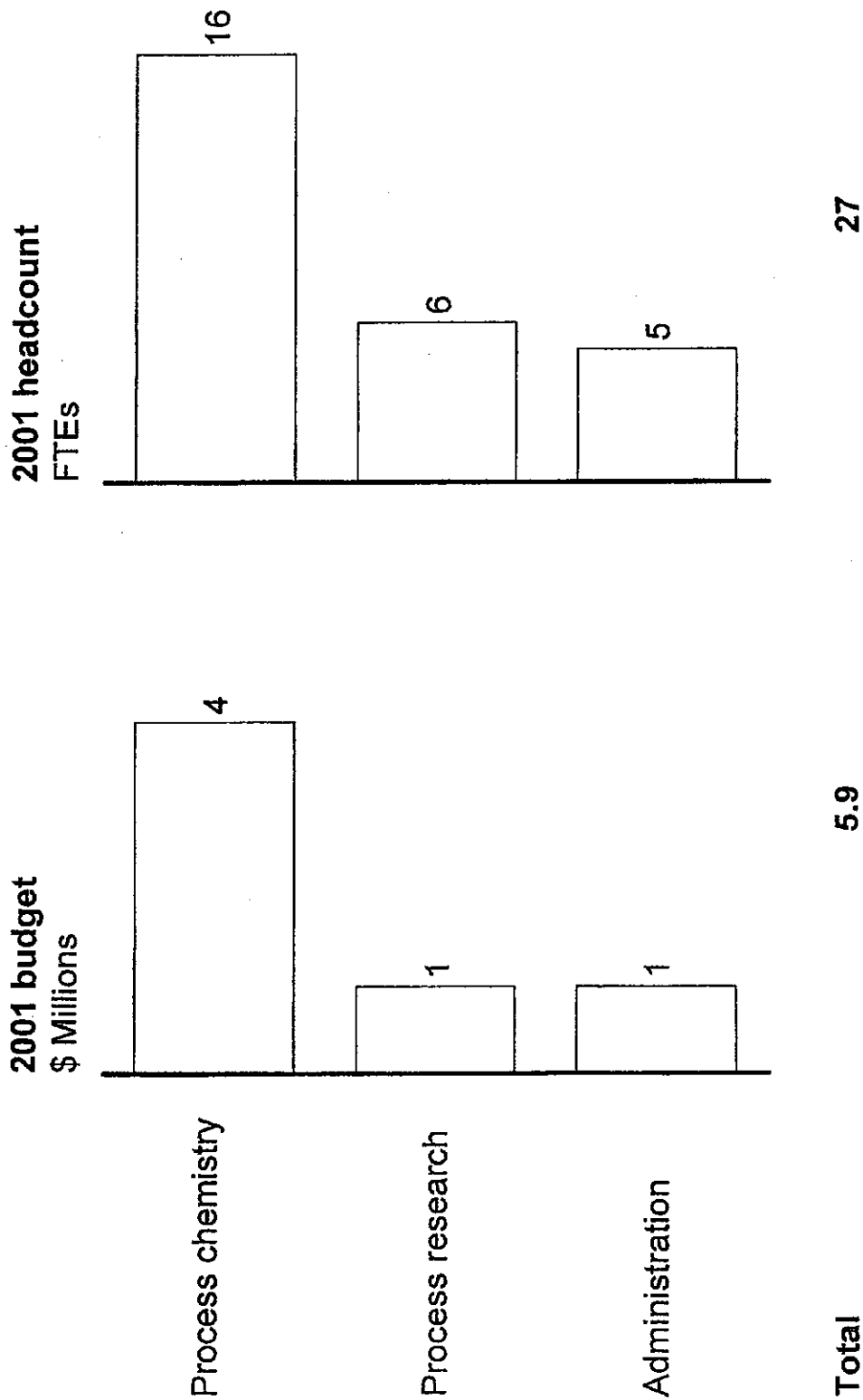
Source: GPRD Finance

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ABBOTT PARK DISCOVERY – CHEMICAL SCIENCES

\$ Millions; FTE

PRELIMINARY

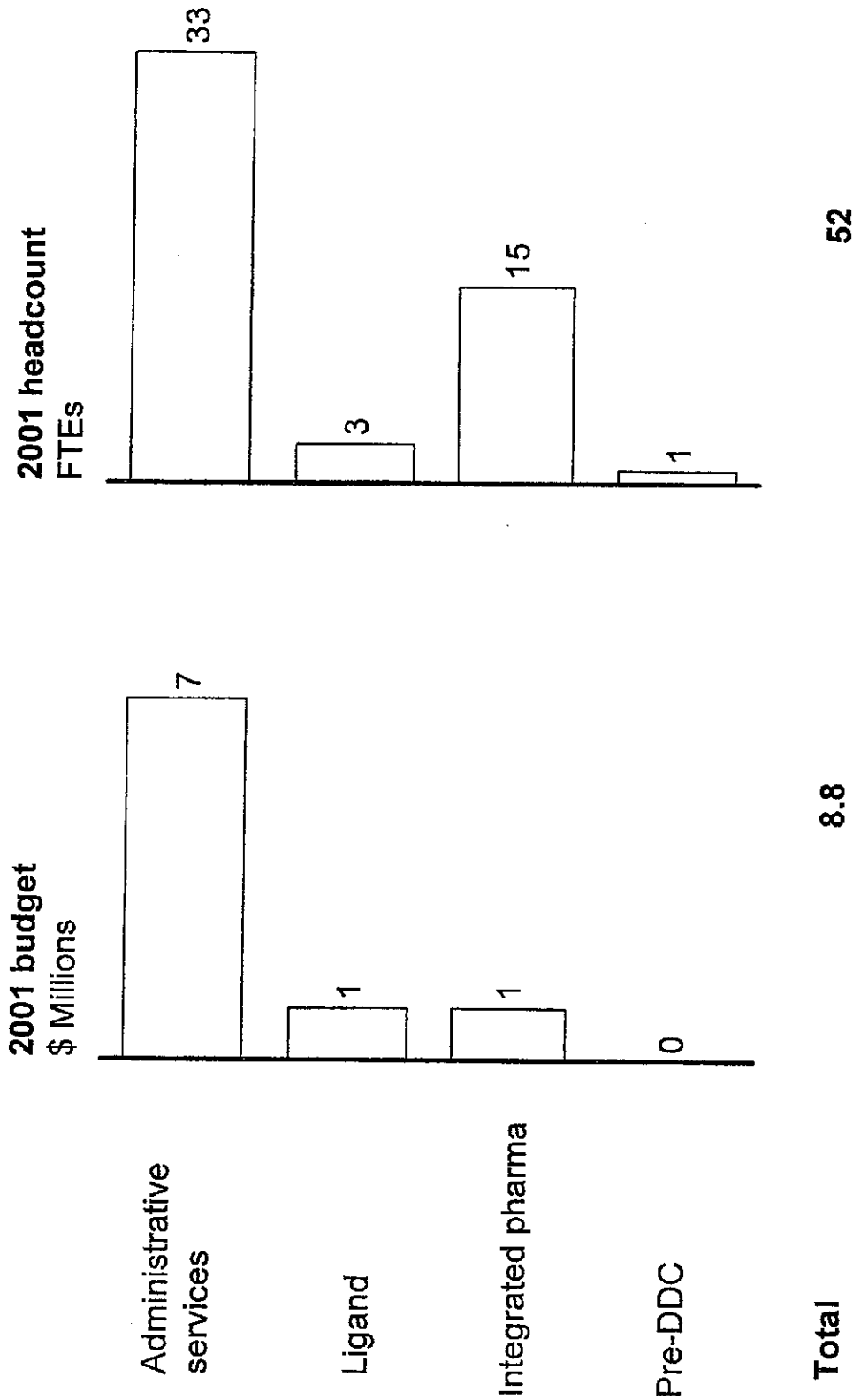


Source: GPRD Finance

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PRELIMINARY

ABBOTT PARK DISCOVERY – ADMINISTRATION/OTHER \$ Millions; FTE



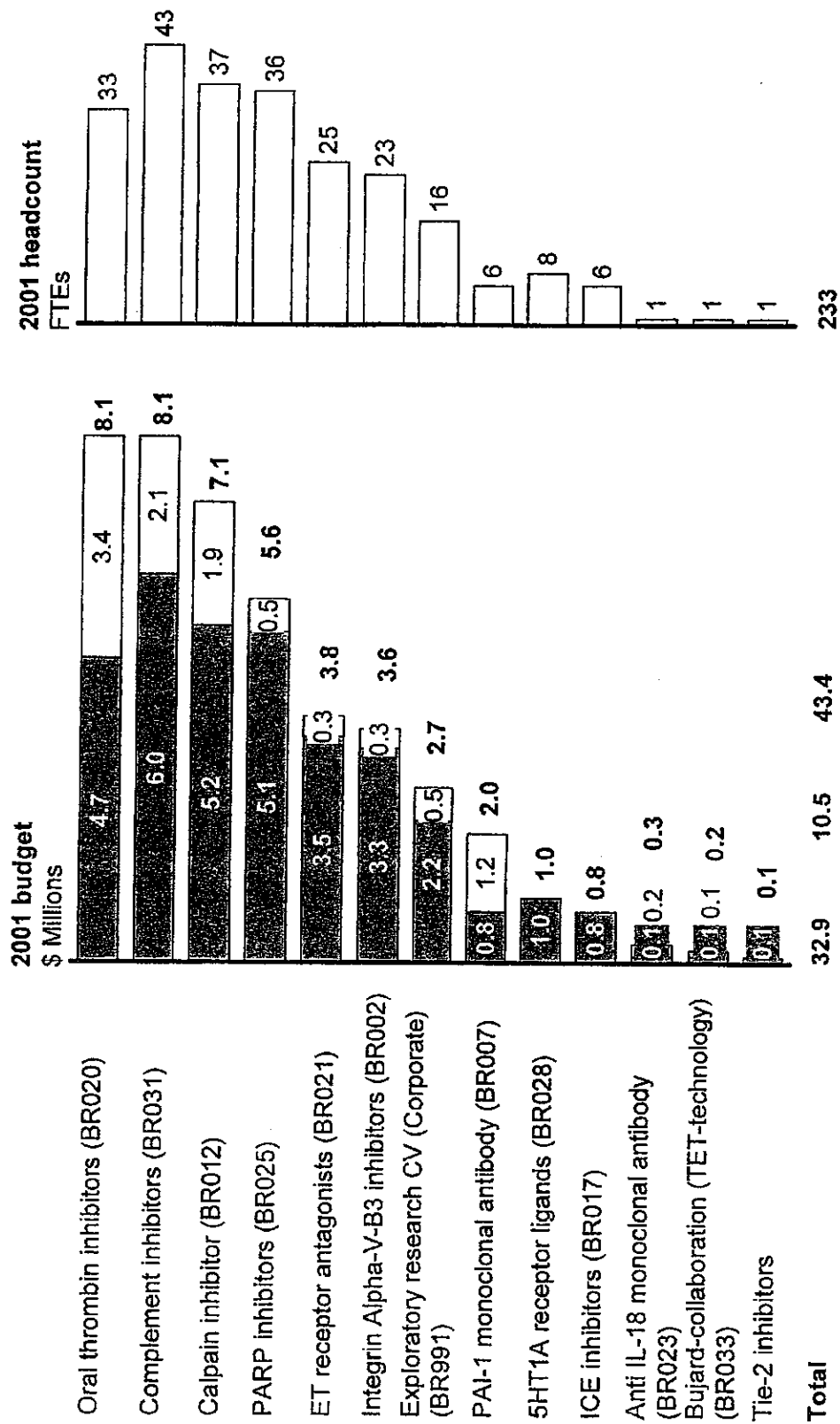
Source: GPRD Finance

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APRIL UPDATE

Internal
External



Source: GPRD finance

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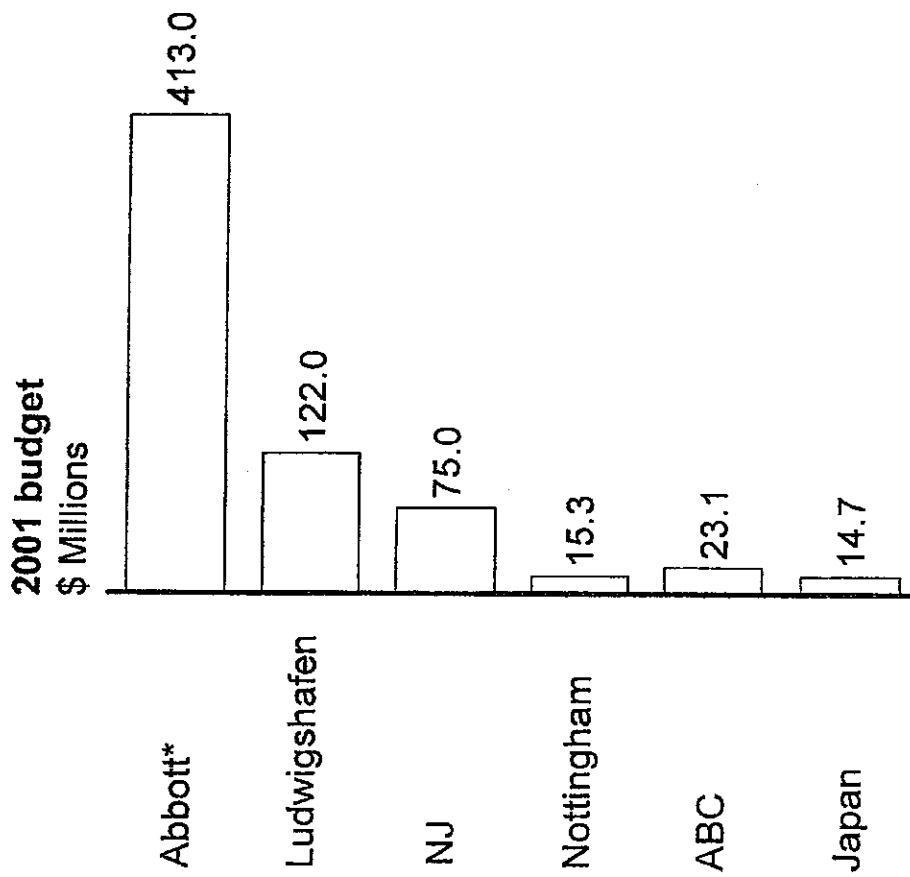
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APPROXIMATE

SUMMARY OF DEVELOPMENT RESOURCE ALLOCATION BY SITE

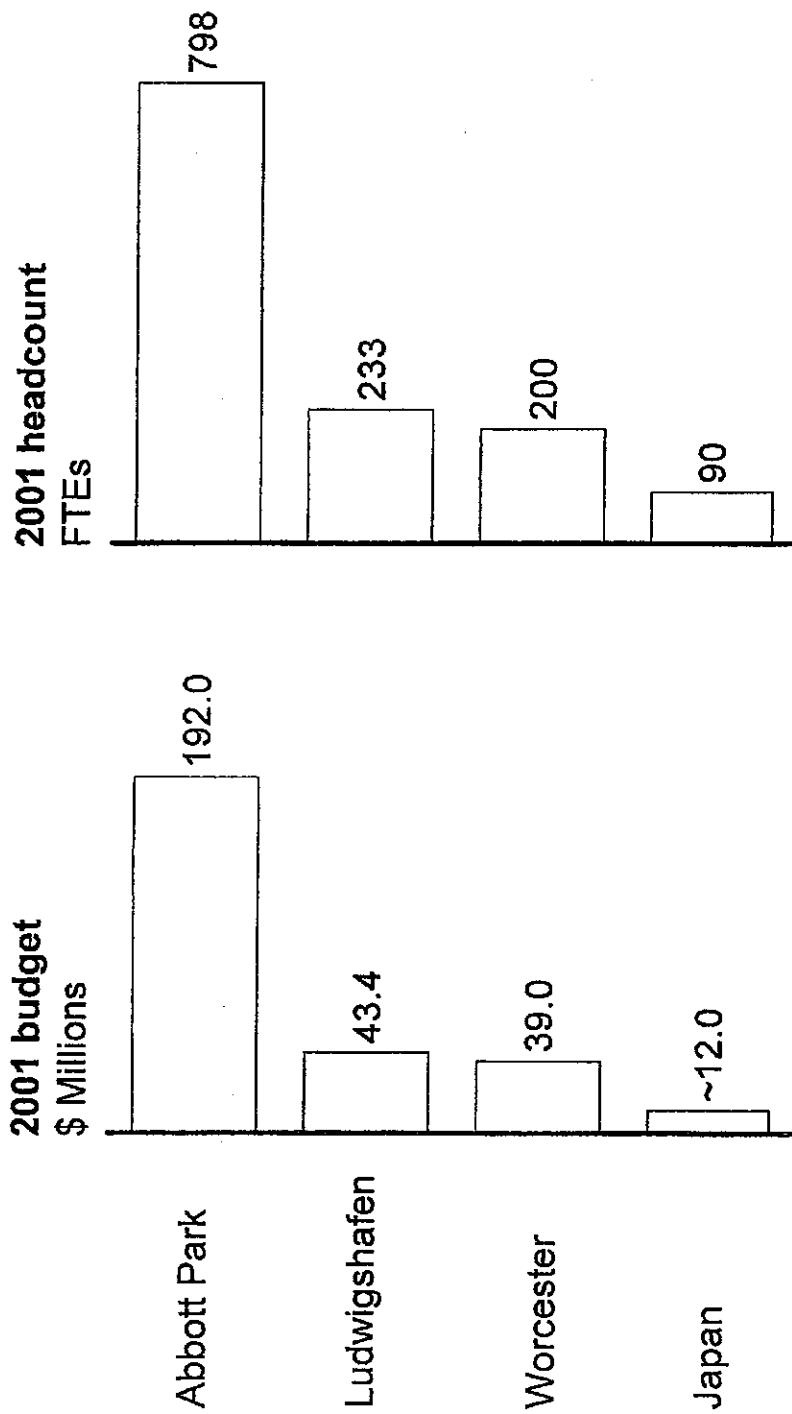


* Mostly Lake County; includes worldwide clinical trials
Source: GPRD Finance; Ludwigshafen Finance

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PRELIMINARY

SUMMARY OF DISCOVERY RESOURCE ALLOCATION BY SITE



Source: GPRD Finance

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DEVELOPMENT PROJECT DECISION TEMPLATE – ANTI-INFECTIVES

Project	Continue	Terminate	Next steps	Responsibility
ABT-773 (ketolide)				
Kaletra				
ABT-492 (quinolone)				
Clarithromycin				
Omnicef				
Ritonavir				

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DEVELOPMENT PROJECT DECISION TEMPLATE – IMMUNOSCIENCE

Project	Continue	Terminate	Next steps	Responsibility
D2E7				
J695				
Segard				
Gengraf				
Honkunalin tape				

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DEVELOPMENT PROJECT DECISION TEMPLATE – ONCOLOGY

Project	Continue	Terminate	Next steps	Responsibility
ABT-627 (endothelin)				
ABT-510 (TSP-1)				
ABT-751 (anti-mitotic)				
ABT-518 (MMPI)				

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DEVELOPMENT PROJECT DECISION TEMPLATE – CARDIOLOGY/THROMBOSIS

Project	Continue	Terminate	Next steps	Responsibility
Darusentan				
Propafenone				
Clivarine				
Fenofibrate				
Tarka				

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**DEVELOPMENT PROJECT DECISION TEMPLATE –
METABOLIC/DIABETES/OBESITY**

Project	Continue	Terminate	Next steps	Responsibility
Sibutramine				
T4/T3				
Synthroid				

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DEVELOPMENT PROJECT DECISION TEMPLATE – PAIN

Project	Continue	Terminate	Next steps	Responsibility
Dilaudid				
ABT-594				
Hydrocodone				
ABT-963 (cox II)				
Vicoprofen				

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DEVELOPMENT PROJECT DECISION TEMPLATE – NEUROSCIENCE

Project	Continue	Terminate	Next steps	Responsibility
Depakote				
BSF 201640				
ABT-089 (ADHD)				

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DEVELOPMENT PROJECT DECISION TEMPLATE – RENAL

Project	Continue	Terminate	Next steps	Responsibility
PEG-Hirudin				

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DEVELOPMENT PROJECT DECISION TEMPLATE – UROLOGY

Project	Continue	Terminate	Next steps	Responsibility
ABT-598 (KCO)				
BSF 420627				

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DEVELOPMENT PROJECT DECISION TEMPLATE – GI

Project	Continue	Terminate	Next steps	Responsibility
AU 224				
Ganaton				

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DISCOVERY PROJECT DECISION TEMPLATE – NUDOR

Project	Continue	Terminate	Next steps	Responsibility
Urology research				
Purinergic mod.				
CCM				
Exploratory urology				
Exploratory neurobiology				
CNS research				
Chemistry				

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DISCOVERY PROJECT DECISION TEMPLATE – CANCER

Project	Continue	Terminate	Next steps	Responsibility
Angiogenesis				
F-Tase				
HDAC				
Apoptosis				
Exploratory cancer				
Urokinase				
Anti-mitotic				
Biology				
Chemotherapeutics				

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DISCOVERY PROJECT DECISION TEMPLATE – INFECTIOUS DISEASE

Project	Continue	Terminate	Next steps	Responsibility
Anti-bacterial chemistry				
Anti-viral				
Anti-bacterial biology				
General microbiology				

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**DISCOVERY PROJECT DECISION TEMPLATE –
ADVANCED TECHNOLOGY**

Project	Continue	Terminate	Next steps	Responsibility
Combinatorial chemistry				
Structural biology				
Screening				
Genomics				
Automation				
Structural chemistry				
Molecular div/ patent				

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DISCOVERY PROJECT DECISION TEMPLATE – MDR

Project	Continue	Terminate	Next steps	Responsibility
Cell biology				
Diabetes				
New targets				
Karo biology				

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DISCOVERY PROJECT DECISION TEMPLATE – CHEMICAL SCIENCES

Project	Continue	Terminate	Next steps	Responsibility
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Process chemistry				
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Process research				
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DISCOVERY PROJECT DECISION TEMPLATE – ADMINISTRATION/OTHER

Project	Continue	Terminate	Next steps	Responsibility
Ligand				
Integrated pharma				
Pre-DDC				

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SYNERGIES WITH ABBOTT'S OTHER BUSINESSES

Therapeutic area	Synergies
Anesthesia	<ul style="list-style-type: none"> • Hospital presence in OR and ICU creates opportunities for launching/ optimizing acute care cardiovascular products and for pain products • Infusion devices
Anti-infectives	<ul style="list-style-type: none"> • Genotype/phenotype monitoring with ADD
Cardiology/thrombosis	<ul style="list-style-type: none"> • Potential opportunities in drug/device combinations (e.g., drug-coated stents, thrombolysis-related devices, etc.)
Immunosciences	<ul style="list-style-type: none"> • HPD Breonics (organ preservation for transplant) • Pain franchise – OA and RA • Discovery synergy with oncology • Nutritional (e.g., CD, renal dysfunction in transplant)
Metabolic/diabetes/obesity	<ul style="list-style-type: none"> • Joint product offerings with Ross (Glucerna, Ensure) and MediSense (Precision QID, SoftTac) • Co-develop new products with Ross, MediSense, ADD, and Pharmacogenetics • Bringing Tricor into franchise
Neuroscience	<ul style="list-style-type: none"> • Multiple synergies with other franchises <ul style="list-style-type: none"> – ADD: development of a diagnostic for Alzheimer's disease – Oncology: an additional channel for sales of anti-depressants – Diabetes: Potential use of H3 in obesity – Pain: synergies in molecular targets and neural systems beginning at the discovery level – Immunoscience: potential for Ab-based therapies and involvement of inflammatory mediators in neuropsychiatric diseases

Source: Strategy retreat template

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SYNERGIES WITH ABBOTT'S OTHER BUSINESSES (CONTINUED)

Therapeutic area	Synergies
Oncology	<ul style="list-style-type: none"> • Diagnostic and therapeutic antibodies • Tumor load testing • Pharmacodynamics and pharmacogenomics • Target therapy to tumor genotype
Pain	<ul style="list-style-type: none"> • Pain is associated with multiple other therapeutic areas (e.g., cancer, diabetes, neuroscience, and urology) • Discovery synergies with urology and neuroscience • Overlap with perioperative/anesthesia, acute care injectables, and animal health
Renal care	<ul style="list-style-type: none"> • Multiple combinations possible <ul style="list-style-type: none"> – Kidney disease and diabetes and diagnostics and CV – Vascular protection and CV device – ARF genomics and diagnostics and GPRD genomics – Erythropoietin and oncology
Urology	<ul style="list-style-type: none"> • Overlap of ED/FSD drugs with diabetes franchise • Overlap of urologic pain drugs with analgesia and/or any primary care franchise

Source: Strategy retreat template

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PROPOSED COMMUNICATION OF DECISIONSFOR DISCUSSION

Audience	Key messages	Vehicle	Timing	Responsibility
<ul style="list-style-type: none"> • Senior management 	<ul style="list-style-type: none"> • Key TAs going forward • Site decisions/implications • Portfolio decisions (discovery and decisions) • Next steps 	<ul style="list-style-type: none"> • E-mail or conversation 	May 8	<ul style="list-style-type: none"> • J. Leiden
<ul style="list-style-type: none"> • R&D sub-teams 	<ul style="list-style-type: none"> • Key TAs going forward • Site decisions/implications • Portfolio decisions • Timing of implementing portfolio decisions • Additional second set of synergy targets 	<ul style="list-style-type: none"> • R&D Steering Committee meeting 	May 8*	<ul style="list-style-type: none"> • J. Leonard • D. Norbeck • X. Frapaise
<ul style="list-style-type: none"> • VP TAs • Venture heads, global project management 	<ul style="list-style-type: none"> • Key TAs going forward • Site decisions/implications • Portfolio decisions • Timing of implementing decisions • HR issues/implications 	<ul style="list-style-type: none"> • One-on-one or group meeting 	May 8	<ul style="list-style-type: none"> • J. Leonard

* Currently scheduled for May 10 but could not be moved up to communicate decisions

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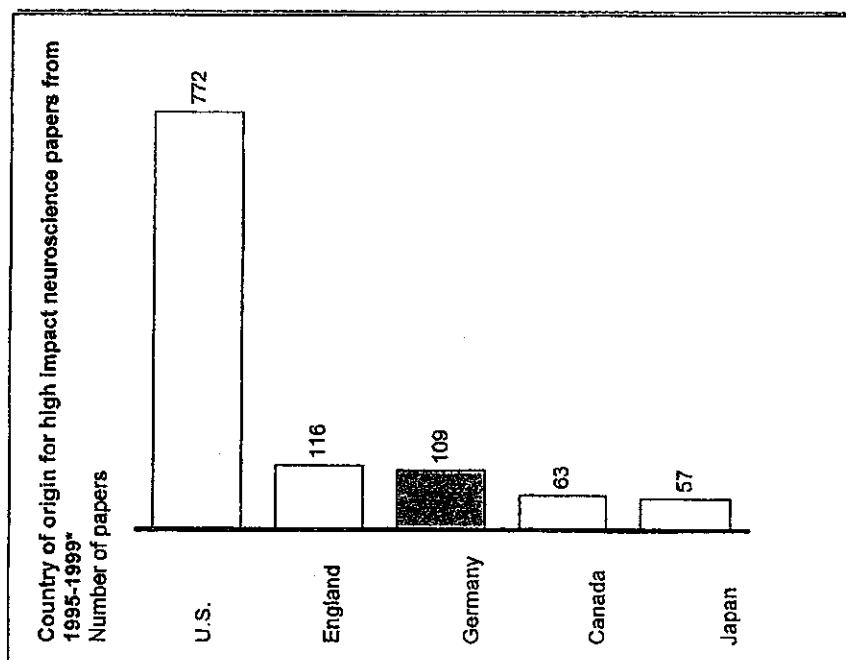
PROPOSED COMMUNICATION OF DECISIONS (CONTINUED)FOR DISCUSSION

Audience	Key messages	Vehicle	Timing	Responsibility
<ul style="list-style-type: none"> • Venture/project teams 	<ul style="list-style-type: none"> • Key TAs going forward • Site decisions/ implications • Portfolio decisions • Timing of implementing decisions • HR issues/implications 	<ul style="list-style-type: none"> • Venture team meetings 	By May 11	<ul style="list-style-type: none"> • Venture heads
<ul style="list-style-type: none"> • Discovery TA heads 	<ul style="list-style-type: none"> • Key TAs going forward • Site decisions/ implications • Portfolio decisions • Timing of implementing decisions • HR issues/implications 	<ul style="list-style-type: none"> • One-on-one or group meeting 	May 8	<ul style="list-style-type: none"> • D. Norbeck
<ul style="list-style-type: none"> • Discovery project teams 	<ul style="list-style-type: none"> • Key TAs going forward • Site decisions/implications • Portfolio decisions • Timing of implementing decisions • HR issues/implications 	<ul style="list-style-type: none"> • Project or TA team meetings 	By May 11	<ul style="list-style-type: none"> • Discovery TA heads
<ul style="list-style-type: none"> • Site leaders <ul style="list-style-type: none"> – ABC – Japan – Ludwigshafen – Mt. Olive – Nottingham 	<ul style="list-style-type: none"> • Key TAs going forward • Site decisions/implications • Portfolio decisions • Timing of implementing decisions • HR issues/implications 	<ul style="list-style-type: none"> • One-on-one conversations 	By May 11	<ul style="list-style-type: none"> • J. Leiden

CH-CH-228013-013jb/aARD

TOP NEUROSCIENCE RESEARCH CENTERS

PRELIMINARY



German Institutes with most high impact neuroscience papers from 1995-1999*		
Institute	Location	Number of papers
Max Planck Institute of Psychiatry	Munich, German	14
Max Planck Institute of Medical Research	Heidelberg, Germany	11
University of Freiburg	Freiburg, Germany	8
University of Munich	Munich, Germany	6
University of Tübingen	Tübingen, Germany	6
Christian-Albrechts-University of Kiel	Kiel, Germany	5
Max Planck Institute for Brain Research	Frankfurt, Germany	4
University of Heidelberg	Heidelberg, Germany	4
Central Institute for Mental Health	Mannheim, Germany	3
Max Planck Institute for Biophysical Chemistry	Göttingen, Germany	3
Max Planck Institute for Neurobiology	Martinsried, Germany	3
Technical University of Munich	Munich, Germany	3
University of Göttingen	Göttingen, Germany	3
University of Konstanz	Konstanz, Germany	3

* The high-impact papers are determined by frequency of citation – the 200 most frequently cited papers through 2000 from each of the following years, 1995, 1996, 1997, 1998, and 1999, were then determined. The list was generated by identifying the institute affiliated with the author(s) of these papers. The neuroscience publications compiled by the Institute for Scientific Information tend to be focused more on basic science (e.g., *Nature*) than clinical science (e.g., *New England Journal of Medicine*)

Source: Institute for Scientific Information (ISI); interview with manager of contract research at ISI

APRIL UPDATE

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PROJECTS BY TA (CONTINUED)
\$ Millions

APRIL UPDATE

TA	Project	2001 budget	2001 shut-down cost		
			Internal	External	Total
• Immunology	• D2E7	102.7	?	?	?
	• Gengraf	2.5	0.7	1.2	1.9
	• Hokunalin Tape	0.0	0.0	0.0	0.0
	• J695	14.0	3.6	6.6	10.2
	• SEGARD	11.9	6.0	5.9	11.9
	Total	131.1			
• Metabolic	• Sibutramine	26.0	7.5	13.9	21.4
	• T4/T3	9.3	?	?	?
	Total	35.3			
• Neurology	• ABT-089 (ADHD)	0.9	0.6	0.0	0.6
	• BSF 201640	(2.3)	0.0	0.0	0.0
	• Depakote	24.1	10.6	5.5	16.1
	Total	22.7			
• Oncology	• ABT-510 (TSP-1)	10.8	5.9	0.2	6.1
	• ABT-518 (MMP1)	7.1	4.4	0.2	4.6
	• ABT-627 (Endothelin)	38.4	12.6	2.1	14.7
	• ABT-751 (Anti-mitotic)	8.3	3.5	0.0	3.5
	Total	64.6			

Source: GPRD Finance

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APRIL UPDATE

PROJECTS BY TA (CONTINUED)
\$ Millions

TA	Project	2001 budget	2001 shut-down cost		
			Internal	External	Total
• Other	• Synthroid	1.7	?	?	?
	• Vicoprofen	1.2	?	?	?
	• Tarka	1.1	?	?	?
	Total	4.0			
• Pain	• ABT-594	9.3	7.7	1.1	8.8
	• ABT-963 (COX II)	1.3	1.1	0.1	1.2
	• Dilaudid	14.4	?	?	?
	• Hydrocodone	3.4	?	?	?
	Total	28.4			
• Renal	PEG-Hirudin	21.7	?	2.2	?
	Total	21.7			
• Urology	ABT-598 (kco)	5.0	1.4	0.0	1.4
	BSF 420627	4.9	?	?	?
	Total	9.9			
	Grand total	556.3			

Source: GPRD Finance

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IMPACT OF R&D SYNERGIES IDENTIFIED ON LUDWIGSHAFEN

PRELIMINARY

Function	Synergy opportunity	Cost savings		Cumulative headcount reductions in Ludwigshafen		Comments
		2001	2002	2001	2002	
CMC	• Close Ludwigshafen chemical development plant	3.9	9.3	37	37	• Achieving savings identified in 2001 is closely tied to timing of headcount reductions
	• Scale up formulation facility of Ludwigshafen	(0.3)	(5.0)	(23)	(63)	• Significant headcount additions in CMC could be key factor in Workers' Council negotiations
Data management and statistics	• Reduce development operations headcount	0.1	0.2	2	2	• Impact of current plan is likely limited
Discovery	• Close high throughput screening at Ludwigshafen	0.7	4.2	29	29	• Headcount reductions identified are more than any other function
						• Plan is to consolidate operations in Abbott Park
Drug safety	• Move contracted work in Europe to Abbott Park	1.3	1.9	—	—	• Savings dependent upon directing project teams to use internal (Abbott Park) resources
	• Reduce radiochemistry operations	0.2	0.7	5	5	
IM&T	• Eliminate non-critical IT positions	0.1	0.3	3	3	• Most savings are from disentanglement of services from BASF corporate
Medical affairs*	• Reduce health outcomes personnel	0.1	0.2	2	2	• Impact of current plan is likely limited

* Excludes initiatives related to AEGIS conversion and reductions in Phase IV trials
Source: Synergy templates; sub-team leaders; team analysis

CH-CH-228013-013j/aaRD

PRELIMINARY

IMPACT OF R&D SYNERGIES IDENTIFIED ON LUDWIGSHAFEN (CONTINUED)

Function	Synergy opportunity	Cost savings		Cumulative headcount reductions in Ludwigshafen		Comments
		2001	2002	2001	2002	
Phase 1	• Increase utilization of Ludwigshafen Phase 1 unit	0.1	0.2	-	-	• Savings dependent upon ability to control location of Phase 1 trials
	• Reduce pharmacokinetic contractor	-	0.3	-	1	
	• Reduce clinical pharmacology headcount	0.1	0.5	4	4	
	• Defer planned AQS upgrades in Ludwigshafen	0.1	-	-	-	
Regulatory affairs/QA	• Reduce head count in Ludwigshafen and operating expenses in regulatory affairs	0.1	0.3	3	3	• Current plan is to consolidate some regulatory and QA activities in Abbot Park
Venture/global team management	• Reduce head count in project management	0.2	0.5	4	4	• Impact of current plans is likely limited
Total		6.7	13.6	66	27	

Source: Synergy templates; sub-team leaders; team analysis

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APRIL UPDATE

HPD R&D BUDGET

\$ Millions

TA	Project	2001 budget
Perioperative and intensive care	• Precedex	5.7
	• PCA III	2.9
	• Corlopam	6.9
	• Rapid dissolve-RP Scherer	3.1
	• Controlled release hydrocodone	4.4
	• Long acting local/systemic anesthetic	1.0
	• Masimo	0.3
	• All other	3.7
	• Total	28.0
Renal care	• Zemplar Phase IV	0.7
	• Zemplar capsules	10.0
	• Zemplar pediatric ESRD	1.3
	• Calcijex pediatric ESRD	0.6
	• Renal care new candidates	1.4
	• Erythropoiesis product feasibility	2.6
	• Pharmacosmos – next generation IV iron	2.5
	• Pronova (Omacor)	–
	• All other	5.0
	• Total	24.1

Source: HPD finance

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HPD R&D BUDGET (CONTINUED)

\$ Millions

APRIL UPDATE

TA	Project	2001 budget
Oncology/anti-infective	• Na Pro Pacitaxel	-0.8
	• SuperGen – Rubitecan	–
	• Antisoma – Theragyn	7.8
	• ABT-773	–
	• All other	0.2
	• Total	7.2
Vascular	• Perclose	13.7
	• Restenosis inhibition (Biocompatibles)	1.7
	• Low molecular weight heparin delivery	1.4
	• rUK/Abbo utilization	–
	• Abbokinase	10.8
	• rUK	7.4
	• Total	34.9
Critical care	• Q2+	2.3
	• All other	1.2
	• Total	3.5

Source: HPD finance

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HPD R&D BUDGET (CONTINUED)

\$ Millions

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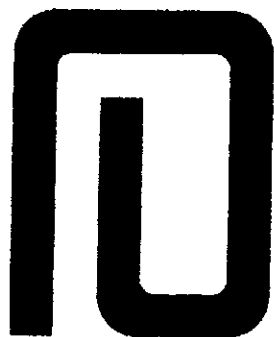
TA	Project	2001 budget
EDDS	<ul style="list-style-type: none"> • Plum at therapy module • Plum at multi-channel • Gemstar • All other • Total 	1.2 4.8 1.2 - 7.3
Acute care injectables	<ul style="list-style-type: none"> • Milrinone IV • Amiodarone • Epinephrine Syringe • All other • Total 	0.2 0.1 1.4 4.8 6.5
All other	<ul style="list-style-type: none"> • Opus • Aegis • Other development • Operations support • Capitalization impact • Total R&D/medical 	1.5 0.3 17.6 45.6 -9.0 161.0

Source: HPD finance

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Leonard Deposition Exhibit 73

P's Exhibit PA



PPG R&D Review

Mar 23, 2006



Leonard EXHIBIT 73
FOR I.D. 6/1/07 1.0ef

Appendix

Agenda for the first meeting

- Analysis of Abbott's pharmaceutical R&D resource allocation
 - History of R&D spend (increases in R and D by year)
 - Spend R vs D
 - Development support vs marketed product support
 - Research spend by TA and Function (Biologics, AT, etc.)
 - Development spend by TA and Function (GPCD, QA, GMA, etc.)
- Historical review of Abbott's pharmaceutical pipeline (2000-2006)
 - What compounds entered development?
 - What compounds progressed in development by Phase?
 - What compounds failed and why?
- Overview of Abbott's current pharmaceutical pipeline
 - ABT #s, target, mechanism of action
 - indication
 - Phase
 - Key go/no-go
 - Origin (internally discovered vs in licensed)
- Discussion and agreement on agenda for next meetings

Proposed agenda for future meetings

Second meeting

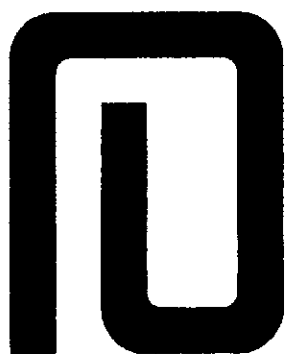
•More detailed review of key programs:

- Oncology pipeline, including Xinlay
- Simdax strategy
- Feno Acid program
- Vicodin CR program
- anti-IL-12/IL-23(ABT-874) program
- Early phase pipeline (Phase I and II)
- Other therapeutic areas as needed (Neuroscience, Pain, Immunology, Metabolics, Antiviral)

Third meeting

- Review and discussion of the consistency and focus of Abbott's pharmaceutical R&D efforts (2000-2006)
- Analysis of the Abbott's pharmaceutical R&D productivity, including benchmark data
- Analysis of the overall quality of Abbott's pharmaceutical R&D pipeline

2002 - 2006 R&D
Expenses



PPG R&D 2002 – 2006 Plan Expense Overview



PPG R&D Objectives (2002-2006)

- Integrate and globalize R&D efforts from multiple divisions and Knoll into single organization.
- Execute the integration, development and commercialization of the Knoll assets to maximize the value of the acquisition.
- Drive Abbott's growth by focusing development spend on late stage development assets and marketed products.
- Focus and competitively fund discovery in areas with large unmet medical need and good research opportunities which are strategically aligned with Abbott's commercial interests – Oncology, Neuroscience/Pain, Immunoscience, Anti-virals, and Metabolics.
- Diversify Abbott's portfolio with biologics based therapeutics.

Executive Summary

- During the 2002-2006 period, Abbott-PPG R&D spend has increased at a 9.1% CAGR.
- Discovery spend has been essentially flat, but is within a competitive range relative to the industry.
- Development spend has been prioritized to optimize sales growth of on- market products.
 - On-Market Product Development: 22.6% CAGR
 - New Indications: 24% CAGR
 - New Formulations: 51% CAGR
 - Other Marketed Product Support R&D: 13% CAGR
 - NME Development: Spend on NME development has declined by 5% annually.
- R&D spending on Humira has increased at a 27% CAGR over the period and has grown to almost 23% of total PPG R&D expense in the 2006 Plan.

PPG R&D 2002-2006 Plan

2002 - 2006 Plan PPG R&D Expense (by spending category)

CAGR%

9.1%

1,432

1,268

1,140

1,111

1,015

10.9%

4.4%

Development

NME Discovery

2006 Plan

2005

2004

2003

2002



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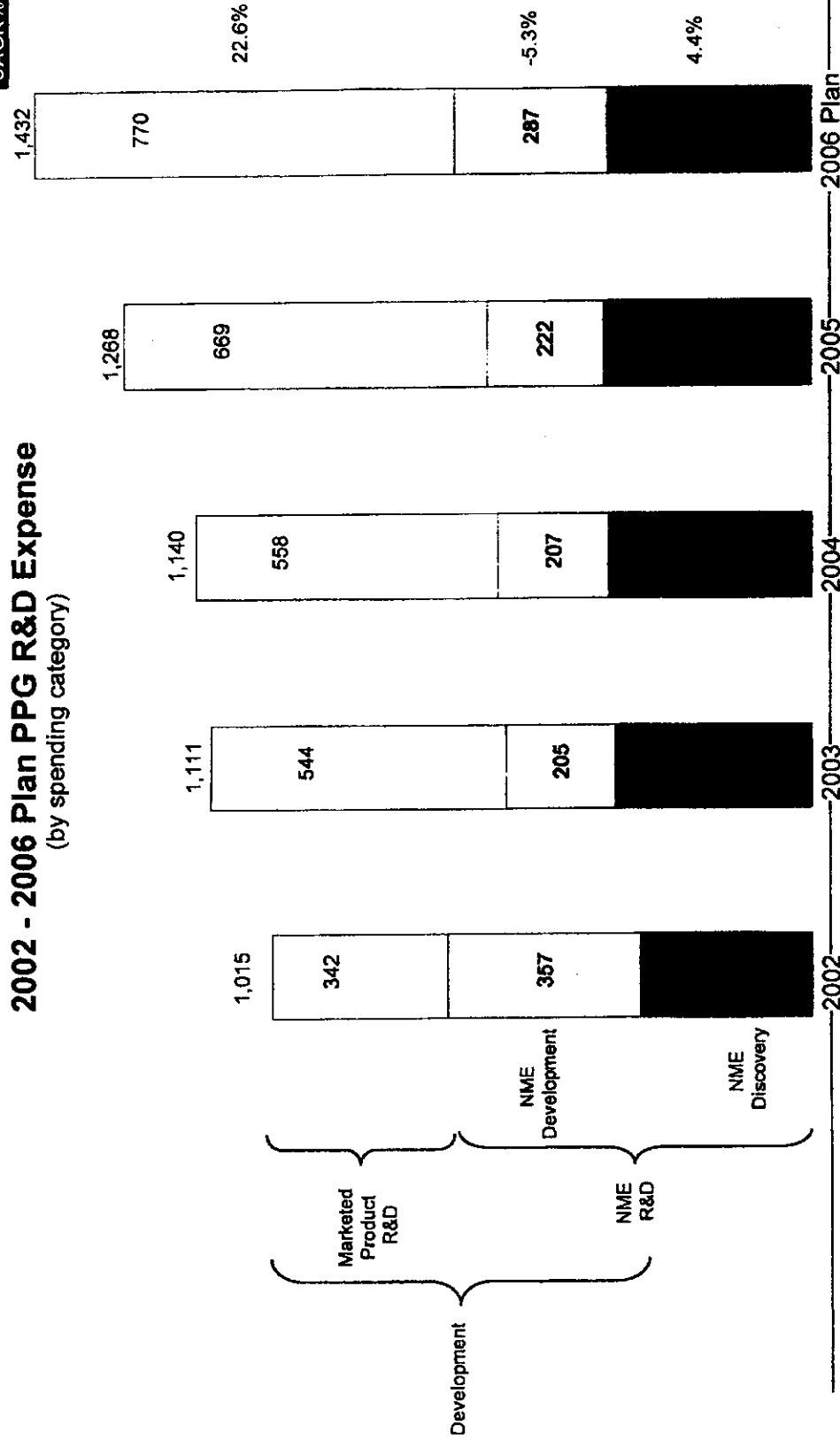
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PPG R&D 2002- 2006 Plan

CAGR²%

2002 - 2006 Plan PPG R&D Expense (by spending category)

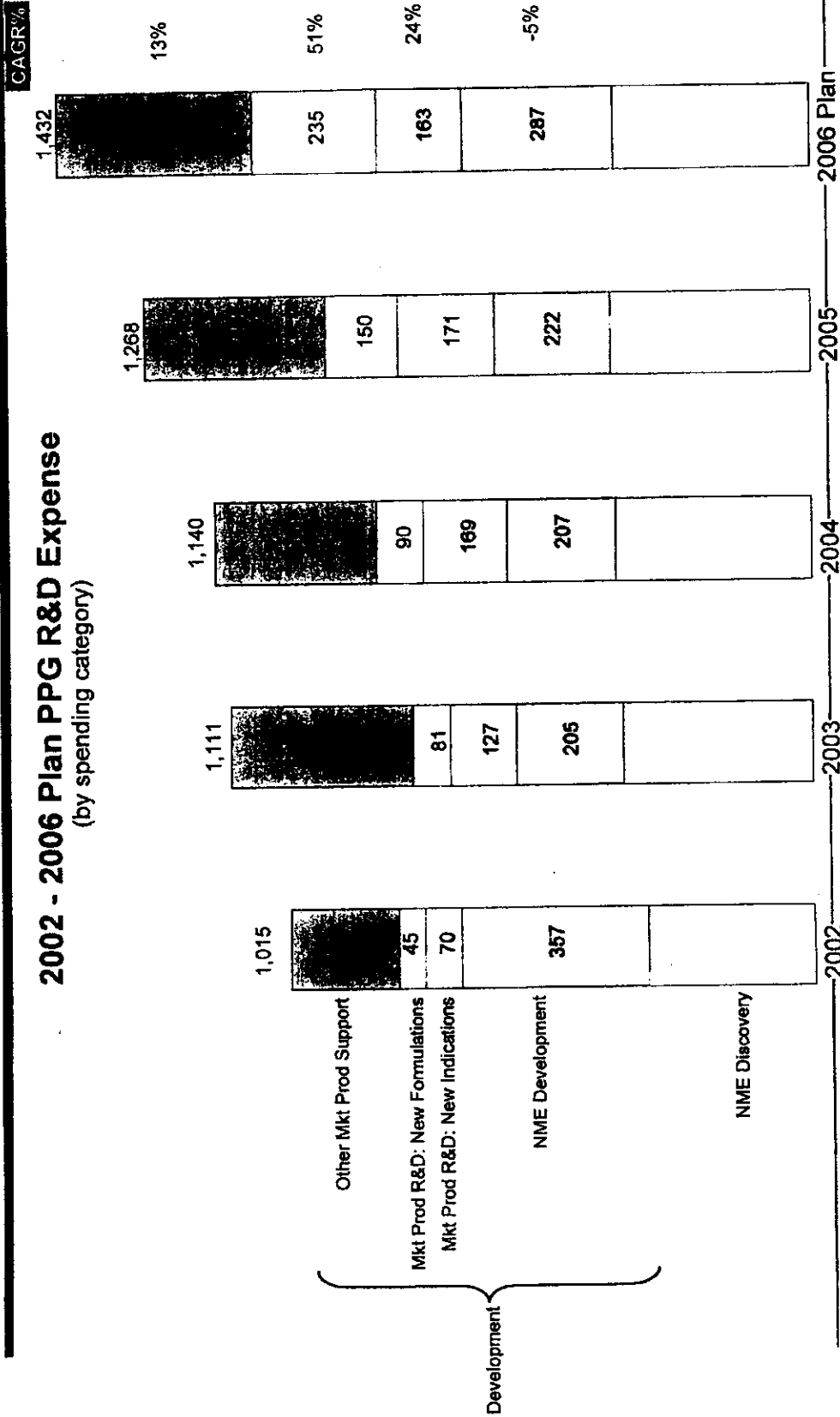


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PPG R&D 2002- 2006 Plan

2002 - 2006 Plan PPG R&D Expense (by spending category)



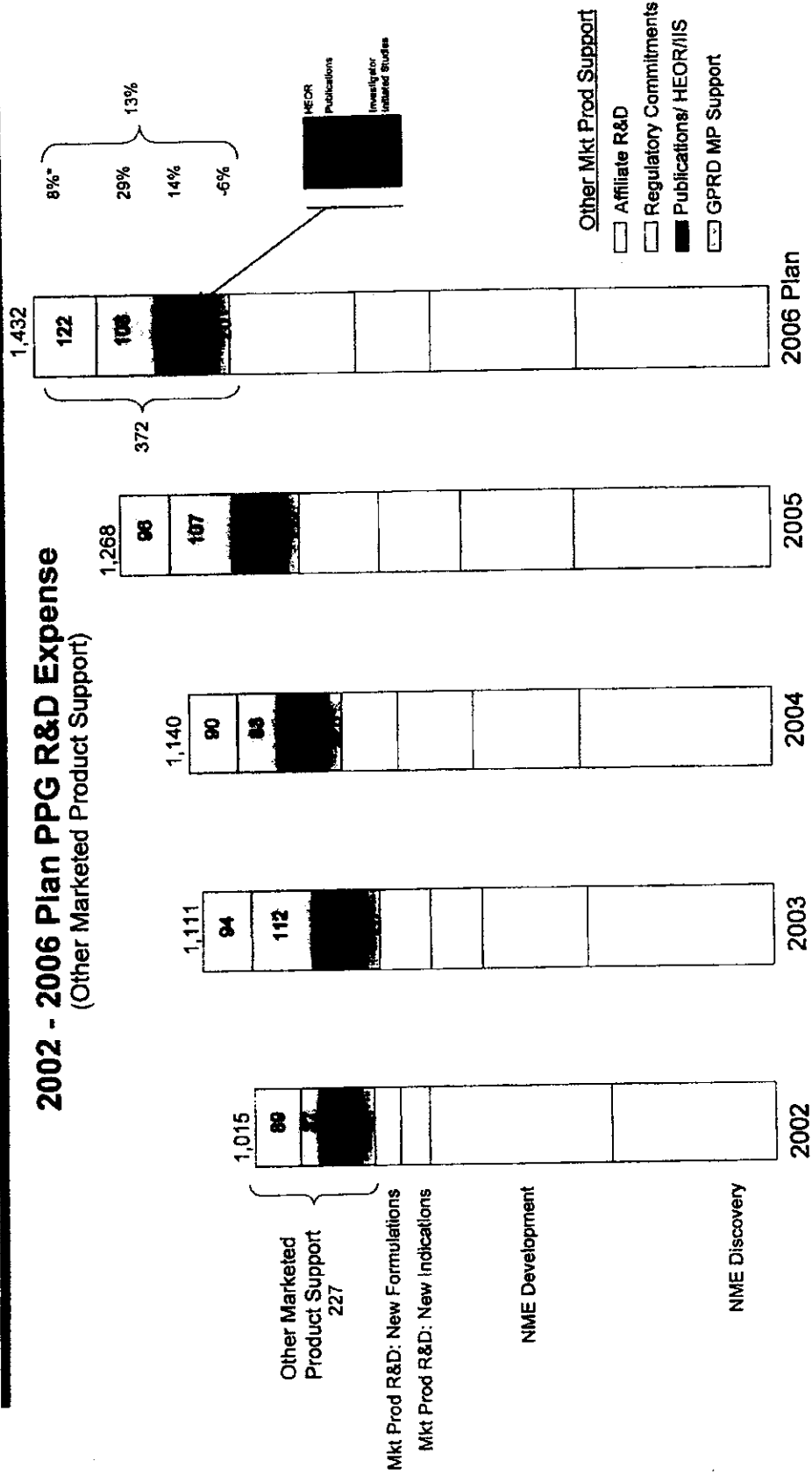
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PPG R&D 2002- 2006 Plan Other Marketed Product Support

CAGR%

2002 - 2006 Plan PPG R&D Expense (Other Marketed Product Support)

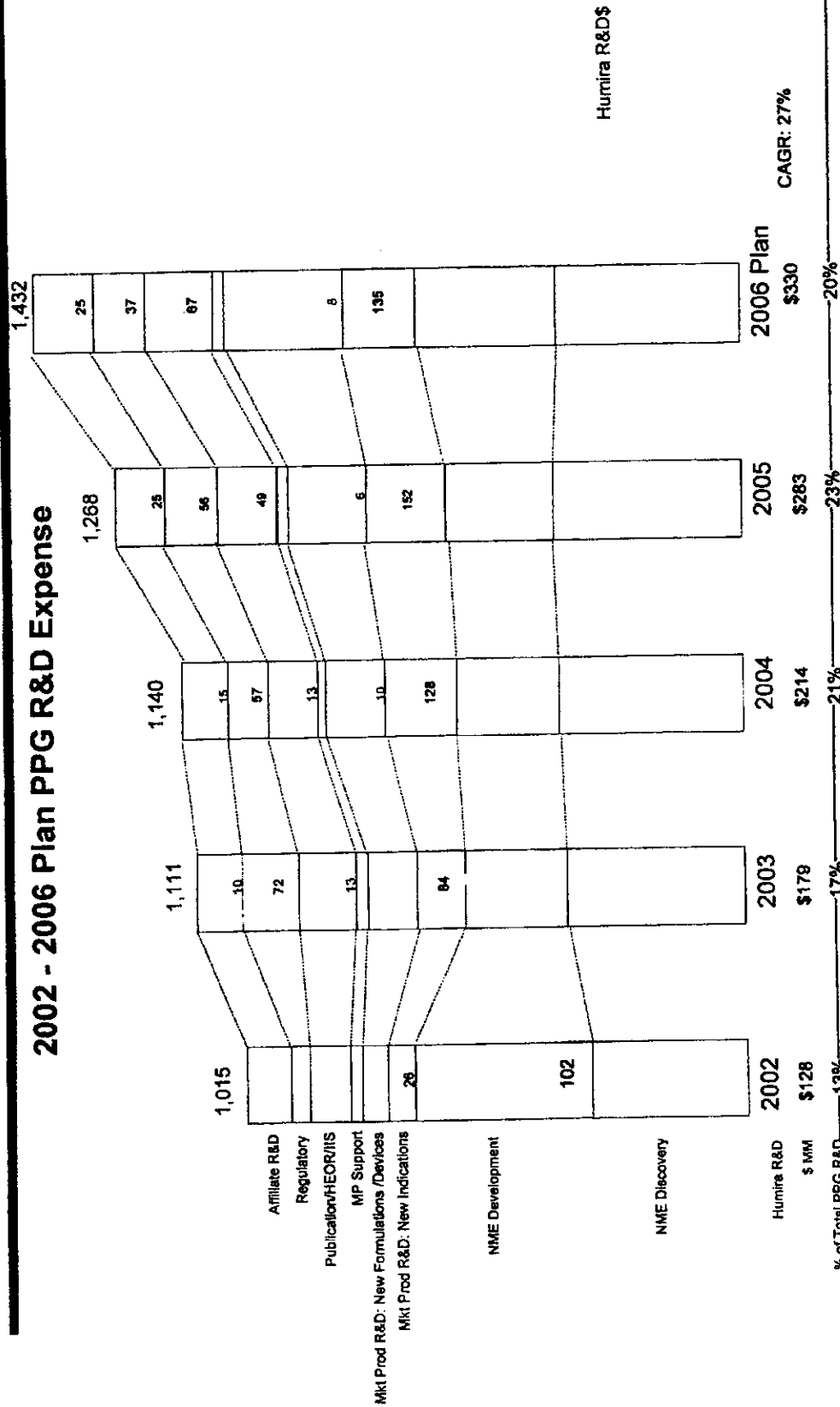


* Excluding the impact of exchange and P&L reclassifications into R&D, the compounded annual growth rate of All Controlled R&D expense from 2002 through 2006 Plan is 3.1%.



PPG R&D 2002 - 2006 Plan Impact of Humira on PPG R&D Expense

2002 - 2006 Plan PPG R&D Expense



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March 23, 2006

2002 – Present
R&D Activity Overview



PPG R&D Activity Overview 2002 – Present



PPG R&D Historical Pipeline Summary (2002 – Present)

- Development of HUMIRA as well as New Indications and New Formulations of Marketed Products has been very successful.
- Development efforts for two key late stage assets, Xinlay and Levosimendan yielded disappointing clinical results.
- Funding in Phase II has primarily focused on HUMIRA, limiting the rapid and complete evaluation of other NMEs in the portfolio.
- From 2002- March 2006, 16 NME's entered the development pipeline from internal discovery efforts
 - Oncology: 7
 - Neuroscience/Pain: 7
 - Metabolics: 1
 - Immunoscience: 1
 - Antiviral: 0
- One NME was in-licensed during this period, NUMAX.

R&D Activity Detail



PPG
R&D Activity Detail
2002 – Present



2002-Present Oncology R&D Activity

\$MM

New Formulations
 New Indications
 NME Development
 NME Discovery

Externally acquired
 Jointly worked on by Abbott Park and ABC Discovery

PPD	Abt 627	ETa	Prostate cancer	NME	Dec-95	Ph III	Ph II	Ph I	Reg	Ph III	Ph II	Ph I	Outlicense
PPD	Abt 510	TSP#1b	Multiple tumor types	NME	Nov-99	Ph I	PC						
PPD	Abt 826	K5	Multiple tumor types	NME	Mar-00	Ph I	PC						
PPD	Abt 751	antimetabolic	Multiple tumor types	NME	Mar-00	Ph I	PC						
PPD	Abt 518	MMF#2	Multiple tumor types	NME	Mar-00	Ph I	PC						
GPRD	Abt 100	Fam transferase#2	Multiple tumor types	NME	Jul-01	PC							
GPRD	Abt 567	TSP#2	Multiple tumor types	NME		PC							
GPRD	Abt 123	RTK	Multiple tumor types	NME		PC							
GPRD	Abt 472	PARP	Multiple tumor types	NME					PC				
GPRD	Abt 737	BCLx (IV)	Multiple tumor types	NME									
GPRD	Abt 007	Epo AB	Anemia from chemo	NME									
GPRD	Abt 869	RTK	Multiple tumor types	NME									
GPRD	Abt 263	BCLx #2	Multiple tumor types	NME									
GPRD	Abt 886	PARP (#2)	Multiple tumor types	NME									

Reason for project termination

- Abt 518: (Undeveloped backup) Competitors with different selectivity and inferior pharmacokinetics failed in phase III. Low funding priority
- Abt 100 (Toxicity) Nerve degeneration seen in multidose toxicity studies
- Abt 567 (Undeveloped backup) Depot formulation developed and then held for life cycle management behind Abt-510
- Abt 123 (Patent) Patent concerns arose post-DDC. Pursuit of license dropped in favor of backup (Abt 869)
- Abt 472 (Pharmacokinetics) Unique human plasma degradation observed. Compound being pursued by Abbott Animal Health
- Abt 737 (Undeveloped backup) Focus switched to orally-active backup (Abt 263)

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March 23, 2006

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Abbott
A Promise for Life

2002-Present
Neuroscience
R&D Activity

Summary

New Formulations
New Indications
NME Development
NME Discovery

Externally acquired

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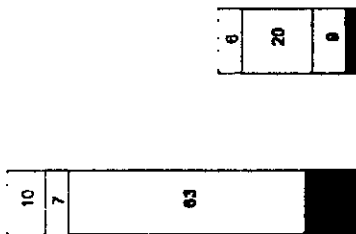
Reason for project termination

- Abt 239 (Safety) Potential QT prolongation and drug/drug interaction. Switched to backup (Abt 834) which appears to have better profile.
- Abt 769 (Toxicity) Teratology findings led to early termination before GLP tox started.
- Abt 834 (Toxicity) Testicular toxicity
- Abt 127 (Pharmacokinetics) Unable to achieve QD dosing, significant drug/drug interactions
- Depakote Psychosis: (Efficacy) Failure to demonstrate efficacy



2002-Present
Anti-Infective
R&D Activity

SMMS



<input type="checkbox"/>	New Formulations
<input type="checkbox"/>	New Indications
<input type="checkbox"/>	NME Development
<input checked="" type="checkbox"/>	NME Discovery

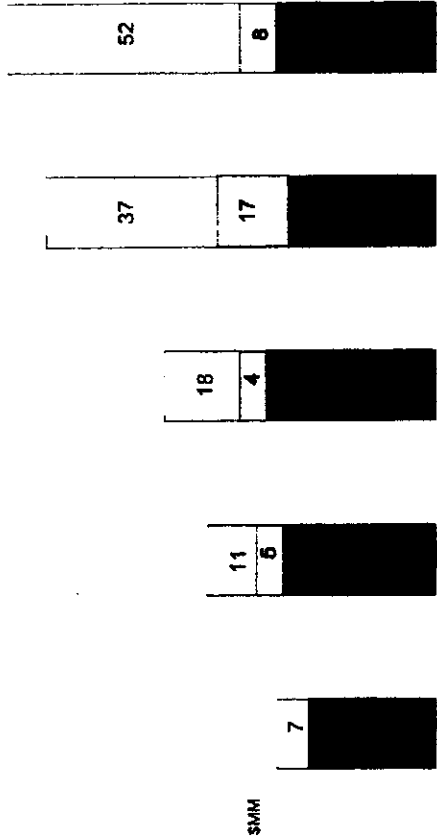
Externally acquired

Product	Active Ingredient	Indication	Marketing Authorization Holder	First Approval	Ph I	Ph II	Ph III	2003	2004	2005	2006
PPD	Abr 773	ketolide	Resp Infection	NME	Mar-97	Ph III					
Enzyme	HSR 903	quinolone	Resp Infection	NME	Feb-94	Ph II	Ph III				
	Abr 482	quinolone	Broad spectrum infection	NME	Nov-99	Ph II					
	GPBD	Abr 210	ketolide	Resp Infection	NME						
Tetracycline	Clari	Macrolide	Clari ER Short Course (EU)	Indication	2001					Approved	
			Clari ER (EU)	Formulation	1995				Approved		
Enzyme			Omnid AOM Double Dose	Indication	2001						
			Omnid OS 250mg	Formulation	2003				Approved		
			Omnicef Reformulation	Formulation	2004						

Reason for project termination

- Abt 773: (Side effects/Efficacy) Narrow therapeutic window with high inter-patient variability
- HSR 903: (Safety/Efficacy) Eosinophilia and questions regarding efficacy
- Abt 492: (Safety/Efficacy) Outstanding safety (crystaluria, liver) and tolerability issues; not differentiated regarding efficacy
- Abt 210: (Strategic) Decision to de-emphasize community-based respiratory anti-infectives
- Omnicef AOM Double Dose:
- Omnicef Reformulation: Viable formulation approach meeting project timeline constraints not identified

2002-Present Anti-Viral R&D Activity



SMM

☐ Externally acquired
☐ New Formulations
☐ New Indications
☐ NME Development
☐ NME Discovery

Product	Indication	Formulation	Year	Ph II	Ph III	Approved (US)	Approved (EU)	PC	PC	PC
PPD	Anti-Retroviral	Simplification / Mono Tx	2003							
		Meltrex (1st gen)	2000							
		QD Dosing (US)	2002							
		Meltrex (2nd gen)	2005							
		Pediatric Tablet	2006							
PPD	Anti-Retroviral	Meltrex Tablet	2006							

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Abbott
A Promise for Life

2002-Present Metabolic / Diabetes R&D Activity

SMM

Externally acquired

[] New Formulations
 [] New Indications
 [] NME Development
 [] NME Discovery

Externally acquired

Abt 477	carb inh	Obesity	NME	Oct-01	Ph I	PC	Ph I	Outlicense
Abt 441	GR-antagonist	Type II Diabetes	NME			PC	Ph I	Outlicense
Abt 279	DPP-IV	Type II Diabetes	NME				PC	Outlicense
Abt 341	DPP-IV	Type II Diabetes	NME				Ph I	
		Weight loss (Japan - Eisai)	Indication	1998				
		Ped Exclusivity	Indication	2002				
		Renal Impairment	Label change	2003				
		DDI's	Label change	2003				
Sibutramine								

Reason for project termination

- Abt 477 (Efficacy) Inadequate evidence that the mechanism of action would be efficacious from Millenium Ph. I trial
- Abt 441 (Divestiture) Being developed by Karabio

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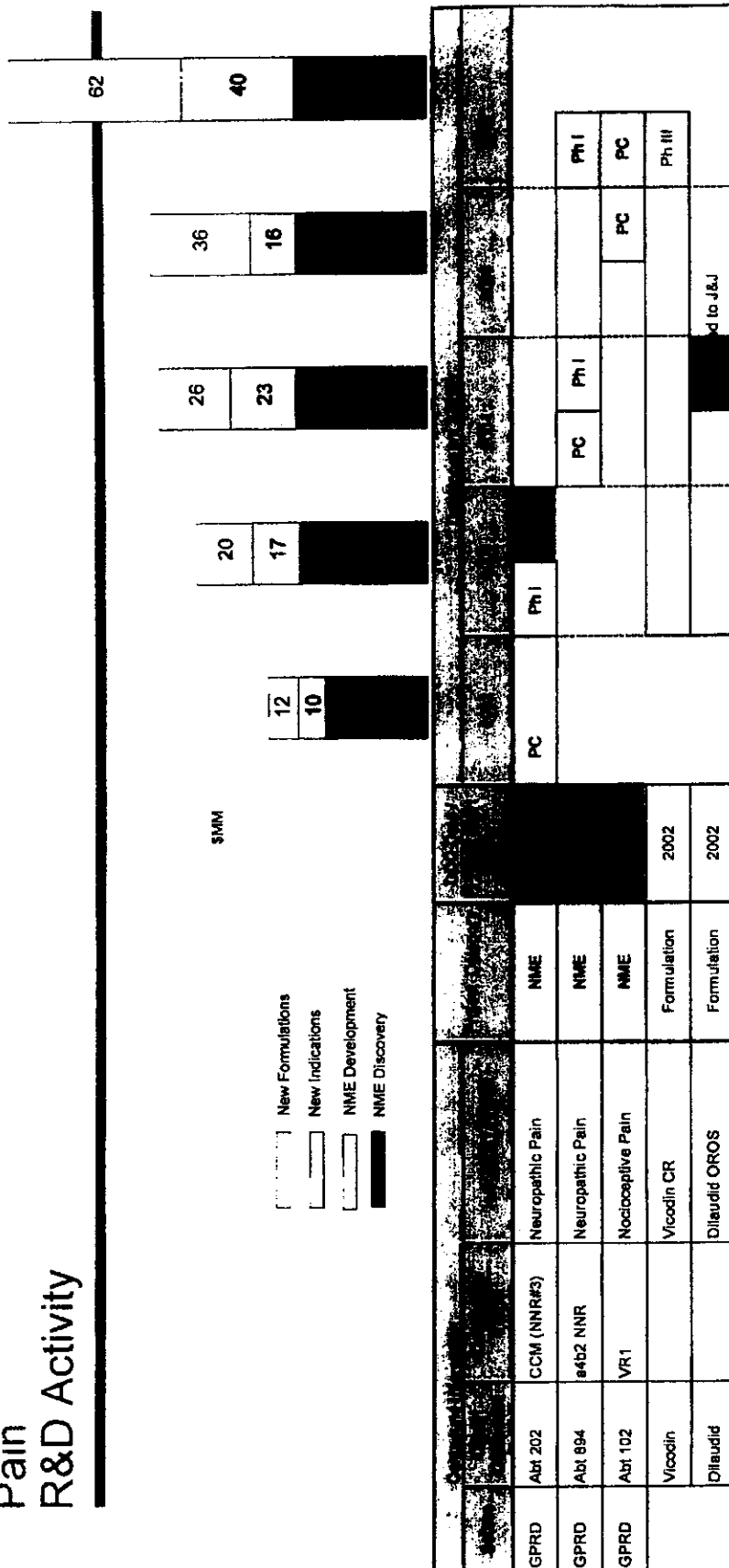
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2002-Present Pain R&D Activity

\$MM

New Formulations
 New Indications
 NME Development
 NME Discovery



Reason for project termination

•Abt 202: (Safety / Tox) Emesis and atrial fibrillation observed

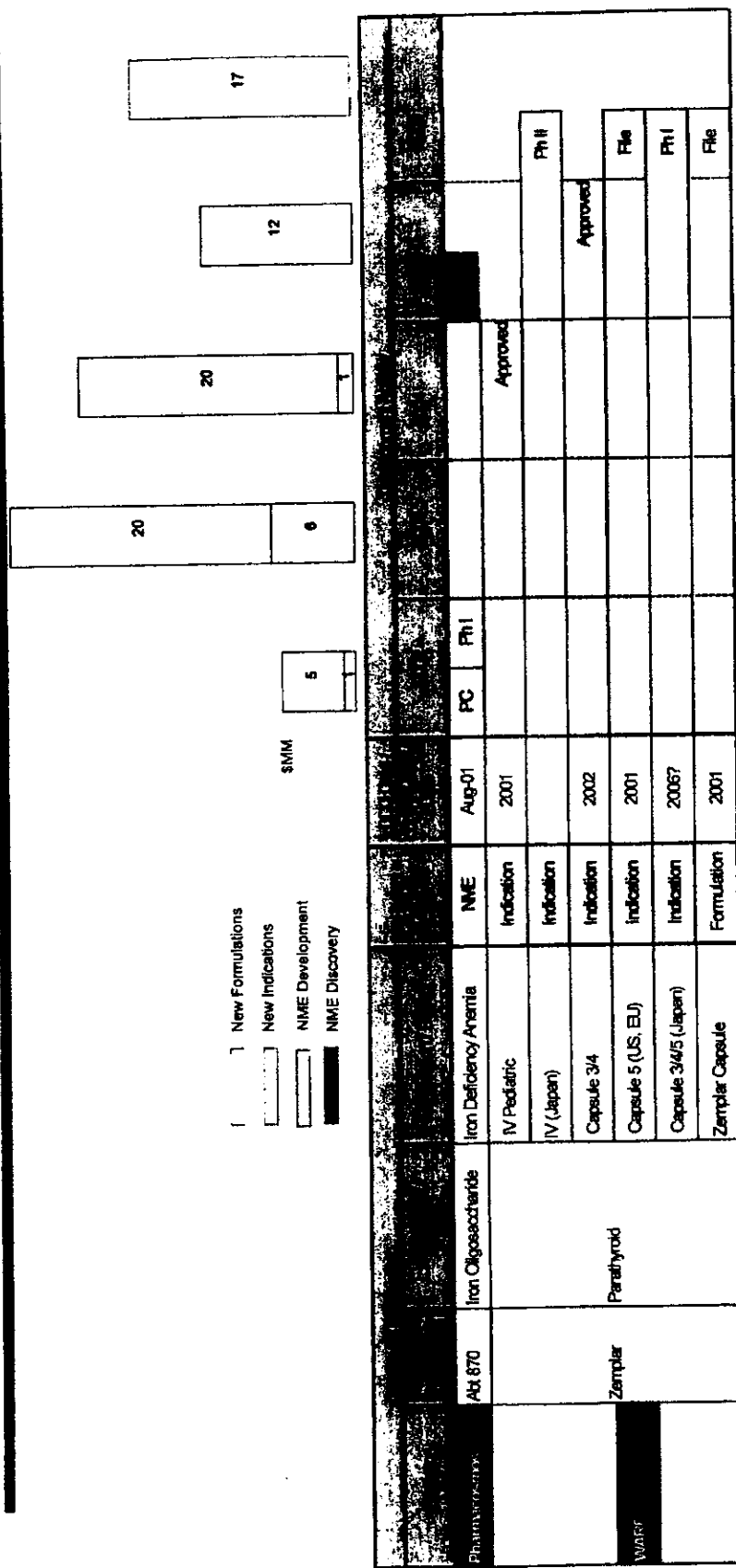
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2002-Present Renal R&D Activity



Reason for project termination

- Abt 870: (Market Potential) Judged to have inadequate market potential compared with other portfolio investment opportunities.



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2002-Present Dyslipidemia R&D Activity

☐ New Formulations
☐ New Indications
☐ NME Development
☒ NME Discovery

3MM

17

21

15

44

108

Product	Indication	Formulation	Year	Phase	Approval	Ph III
Former	Tricor	Formulation	2001	Approved	Approved	TBD
	Tricor NFE	Formulation	2002			
	Tricor FDC	Formulation	2006			
	Feno Acid	Formulation	2002			







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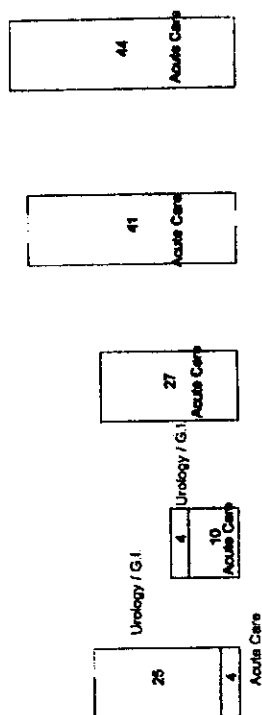
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2002-Present
Urology/ GI / Acute Care
R&D Activity

	New Formulations
	New Indications
	NME Development
	NME Discovery

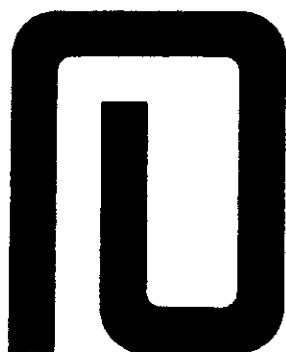
Externally acquired

[illegible]

Reason for project termination

- Abt 724 / Abt 670: (Market Potential / Strategic) Similar reasons as for Abt 724. Strategic decision to curtail future discovery efforts in this area.
- Abt 224: (Strategic) Decision to exit further development in the GI franchise area
- Abt 120: (Safety/Efficacy) Inadequate risk/benefit demonstrated; questionable commercial viability given current stroke diagnostic / treatment paradigm

2006 Pipeline/LRP
Overview



PPG R&D 2006 Current Pipeline Status and LRP Timeline Overview



Current Pipeline Summary

- In 2006 funding is prioritized to support development activities for on market products, late stage NMEs, and the rapid evaluation of DDC candidates.
- Five areas of R&D focus Oncology, Neuroscience, Immunology, Pain and Metabolics have NMEs in development which have the potential to drive future growth.
- Funding for Phase II opportunities remains limited.

Current Pipeline Summary

- Phase III Activity Funded
 - NMEs
 - Xinlay (ABT-627), Cancer; Levosimendan, Heart Failure; NUMAX, RSV
 - New Indications
 - HUMIRA, Psoriasis, Ulcerative Colitis; Depakote, pediatric
 - New Formulations
 - Vicodin CR, Pain; Fenofibric Acid, Dyslipidemia
- Phase II Activity Funded
 - NME
 - ABT-874, MS, Psoriasis; ABT-751, Cancer; ABT-089, Cognition
- Phase II Activity Unfunded
 - NME
 - ABT-925, Schizophrenia; ABT-874, Crohn's Disease
 - New Indications
 - HUMIRA Asthma

Current Pipeline Summary

- Phase I Activity (Funded)
 - NME
 - ABT-869, Cancer; ABT-894 Pain & Cognition
- Phase I Activity (Unfunded)
 - NME
 - ABT-325, Systemic Lupus (SLE)
- Post-DDC Pre-clinical Development Activity (Funded)
 - NME
 - ABT-828, Cancer; ABT-263, Cancer; ABT-888; Cancer; ABT-102, Pain; ABT-560, Cognition; ABT-107, Cognition
 - New Formulations
 - Kaletra-Meltrex 2nd gen., HIV; HUMIRA, Needle Free

Current Pipeline Summary

- Post-DDC Pre-clinical Development Activity (Unfunded)
 - NME
 - ABT-362; SLE
- Out-licensing and/or Partnering Assets
 - Phase II
 - ABT-510, Cancer
 - Phase I
 - ABT-279, Diabetes
 - Post-DDC Pre-clinical
 - ABT-341, Diabetes; ABT-007, Cancer

Current Pipeline LRP Deliverables

- Major Approvals:

- HUMIRA, AS – 2Q06
- HUMIRA, Pen – 4Q06
- HUMIRA, Crohn's disease – 1Q07 (with priority review)
- Xinlay prostate cancer – 3Q07 (with priority review)
- HUMIRA, JRA – 1Q08
- Depakote, pediatric – 1Q08
- HUMIRA, psoriasis – 3Q08
- Fenofibric Acid, dyslipidemia (co-administration claim) – 3Q08
- Vicodin CR, pain – 3Q08
- NUMAX, RSV (developed by MedImmune) – 3Q08
- HUMIRA, ulcerative colitis – 2Q09
- Kaletra-Meltrex 2nd generation, HIV – 2Q09
- Levosimendan acute heart failure – 4Q09/1Q10 (pending additional studies)

Current Pipeline Deliverables

- Next Milestone:

- ABT-751, NSCLC, Phase II/III – 3/2006 Ph II start
- ABT-263, cancer, Pre-clinical/Phase I – 6/2006 File IND
- ABT-828, cancer, Pre-clinical/Phase I – 3Q 2006 File IND
- ABT-894, cognition/pain, Phase I/II - 3Q06 Ph II Go / No Go
- ABT-102, pain, Pre-clinical/Phase I – 3Q2006 Ph I start
- ABT874, MS, Phase II/III – 4Q06 Ph II completion
- ABT-874, PS, Phase II/III – 4Q06 Ph. II completion
- ABT-888, cancer, Pre-clinical/Phase I – 4Q2006 File IND
- ABT-869, cancer, Phase I/II – 12/2006 Ph II start
- ABT-107, cognition, Pre-clinical/Phase I – 1Q 2007 File IND
- ABT-560, cognition, Pre-clinical/Phase I – 2Q 2007 File IND

Potential New DDCs for NME Development in 2006

- Immunoscience (2): IL-18 (Abt-874 backup), S1P1
- Antivirals (1): HCV polymerase
- Neuroscience / Pain (5): D3, VR1, V1b, CB2, H3
- Oncology (1): MTK
- Metabolics (0): Program refocused

2006 Pipeline/LRP
Detail



PPG R&D 2006 Current Pipeline Status and LRP Timeline Detail



2006 Current Pipeline Status and LRP Timeline Oncology

[illegible]

2006 Current Pipeline Status and LRP Timeline Neuroscience

Sponsor	Drug	Indication	Phase	Timeline					Key Milestones
				2007	2008	2009	2010	2011-2016	
PPD	Abt 089	ADHD, Alz Dis, cognition	Ph II					2012	6/2006 (9 month rat study completion) 1Q 2007 (File IND)
GPRD	Abt 107	Cognition, Alz Dis	PC					2014	3Q 2006 (Ph II Go/No Go)
GPRD	Abt 894	ADHD, Alz Dis, cognition	Ph I					2012	25% (ADHD), 15% (Alz)
Kirell	Abt 925	D3 antagonist	Ph II					2013	17%
GPRD	Abt 560	ADHD, Alz Dis, cognition	PC					2014	2Q 2007 (File IND)
Sano	Depakote	Ped Exclusivity	Ph III						1Q 2008 (Regulatory approval)



2006 Current Pipeline Status and LRP Timeline Immunology

Product	Indication	CD	Indication	File	1Q	2Q	3Q	4Q	2007	2008	2009	2010	2011	2012	2013	2014	2015	Regulatory approval
Knoll/ABC				CD					1Q									Regulatory approval
				JRA														File 1Q 2007
				PS														File 1Q 2007
				UC														4Q 2006 (Start Ph III)
				Asthma														Awaiting funding availability
Knoll/ABC				Pan														1 Q 2007 (Regulatory approval)
				Needle Free														12/2006 (Phase I pilot start)
				Multiple Sclerosis														4 Q 2006 (Ph. II completion)
				Psoriasis														4 Q 2006 (Ph. II completion)
				Crohn's														(1Q 2008) Ph. II b completion
GPRD/ABC				SLE (Lupus)														Awaiting funding availability
Medimmune				RSV														Mid 2006 (Ph III Completion)
				SLE (Lupus)														Awaiting funding availability



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Product	Indication	Phase	Timeline	Regulatory Status	Approval Status	Completion Status
Acute Care	Sildenafil	Acute Heart Failure	Phase I/II	4Q	TBD (~50%)	2Q 2008 (Ph. III Go/No Go)
		IV (Japan)	Phase II	1Q	65%	3Q 2008 (Complete Ph. II)
		Capsule 5 (US, EU)	Phase I	1Q	95%	2Q 2008 (sNDA submission)
		Capsule 3/4/5 (Japan)	Phase I	1Q	85%	2Q 2008 (PMDA Meeting)
Renal	Zemplar	Zemplar Capsule	Formulation	1Q	95%	Regulatory approval
		Triclor FDC	Formulation	3Q	50%	Completion of FDC deal
		Feno Acid	Formulation	4Q	85%	1Q 2007 (Ph. III Completion)
Dyslipidemia	Triclor	Fenofibrate	Formulation	1Q	95%	Regulatory approval
					50%	Completion of FDC deal
					85%	1Q 2007 (Ph. III Completion)

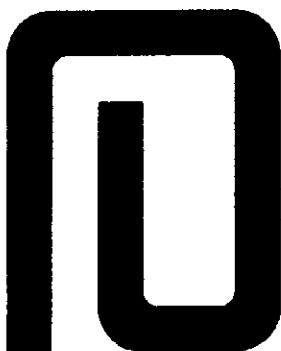
Topics for Further
Discussion

Topics for Future Discussion

- Should additional studies be conducted with Levosimendan in acute and/or chronic heart failure?
- How should key unfunded Phase II opportunities be prioritized in the event budget availability available?
 - Start new Phase II studies HUMIRA asthma, ABT-925 for schizophrenia and Abt 874 (Crohn's)?
 - Retain potential funding availability for continuation of ABT-089 Phase II studies (assuming positive toxicity study results in 6/2006)?
- What direction should we take our Metabolics discovery efforts?
- Should we reassess our risk tolerance for moving forward compounds with unvalidated mechanisms of action (e.g.. Abt 325 and 362 (Lupus))?
- Should we revisit our oncology phase II development strategy (e.g. Abt 510)?

Glossary

Glossary



Glossary

NAME Compound	Therapeutic Area	Lead Indication(s)	Target / Compound Description	Source	DDC Date	Current Status	Other Information
Abi 007	Oncology	Chemotherapy induced anemia	rEPO (Recombinant form of erythropoietin, a naturally occurring compound stimulating red blood cell production)	GPRD	Dec-03	Outlicense candidate	Biologic - biotechnology generated compound
Abi 089	Neuroscience	Attention deficit / hyperactivity disorder (ADHD), Alzheimer's Disease, cognition	α 4 β 2 NNR (Nicotinic Neuronal Receptor)	PPD	Jun-99	Phase II	On hold, pending toxicity study outcome
Abi 100	Oncology	Multiple tumor types	Farnesyl transferase	GPRD	Jul-01	Terminated 2001	
Abi 102	Pain	Nociceptive pain (pain caused from pressure, inflammation, etc)	VR1 (Vanilloid Receptor)	GPRD	Dec-03	Pre clinical	
Abi 107	Neuroscience	Cognition impairment, Alzheimer's Disease	α 7 NNR (Nicotinic Neuronal Receptor)	GPRD	Jul-05	Pre clinical	
Abi 120	Acute Care	Stroke therapy	rUK (Recombinant form of Urokinase, potent anti-coagulant)	PPD / HPD		Terminated 2003	Biologic - biotechnology generated compound
Abi 123	Oncology	Multiple tumor types	RTK (Tyrosine Kinase inhibitor- inhibits blood supply formation of tumors)	GPRD	Dec-02	Terminated 2003	
Abi 127	Neuroscience	Schizophrenia	D3 agonist (D3 is a dopamine receptor)	GPRD	Jun-03	Terminated 2005	
Abi 202	Pain	Neuropathic Pain (pain caused by neuropathic disorders- e.g. diabetes, herpes)	NNR (Nicotinic Neuronal Receptor)	GPRD	Jun-02	Terminated 2003	
Abi 210	Anti-Infectives	Respiratory Infection	Ketolide - next generation macrolide (follow on for Blaxin)	GPRD	Sep-02	Terminated 2002	
Abi 224	Gastro-intestinal	Chronic Idiopathic Constipation - severe, chronic constipation from undetermined cause	5HT ₄ agonist (target in the large intestine which stimulates bowel motility)	Knoll		Terminated 2003	

Glossary (cont.)

NME Compound	Therapeutic Area	Lead Indication(s)	Target / Compound Description	Source	DDC Date	Current Status	Other Information
Abt 239	Neuroscience	Attention deficit / hyperactivity disorder (ADHD), Alzheimer's Disease	H3 (Histamine 3 receptor agonist)	GPRD	Dec-01	Terminated 2002	
Abt 263	Oncology	Multiple tumor types (Small Cell Lung Cancer)	BCLx inhibitor (tumor growth inhibitor first identified in chicken B cell lymphoma)	GPRD	Oct-05		Backup for Abt 737
Abt 279	Metabolics	Type II Diabetes	DPPIV inhibitor (Dipeptidyl peptidase IV inhibitor)	GPRD	Nov-04	Outlicense candidate	
Abt 325	Immunology	Systemic Lupus Erythematosus (SLE) - debilitating immune disorder	anti-IL-18 (targets interleukin 18 pathway which is thought to be involved in SLE)	GPRD/ABC	Jul-03	On Hold	Looking for funding partner
Abt 341	Diabetes / Metabolics	Type II Diabetes	DPPIV inhibitor (Dipeptidyl peptidase IV inhibitor)	GPRD	Nov-05	Outlicense candidate	Backup for Abt 279
Abt 362	Immunology	Systemic Lupus Erythematosus (SLE) - debilitating immune disorder	anti-IL-18 (targets interleukin 18 pathway which is thought to be involved in SLE)	GPRD/ABC	Dec-04	On Hold	Looking for funding partner
Abt 441	Metabolics	Type II Diabetes	GR-antagonist (Glucocorticoid receptor- oral anti diabetic agent)	Karabio	Dec-02	Returned to Karabio	Being developed by Karabio
Abt 472	Oncology	Multiple tumor types	PARP inhibitor (poly ADP ribose polymerase inhibitor - enhances effectiveness of chemo and radiation therapy)	GPRD	Sep-03	Terminated 2005	
Abt 477	Diabetes / Metabolics	Obesity	Carb inh (Carboxypeptidase inhibitor)	Milenium	Oct-01	Terminated 2002	
Abt 492	Anti-Infectives	Broad spectrum Infection	Quinolone class antibiotic	Waukensga	Nov-99	Terminated 2002	
Abt 510	Oncology	Multiple tumor types	TSP (Thrombospondin mimetic peptide that blocks tumor response to several growth factors)	PPD	Nov-99	Outlicense candidate	
Abt 518	Oncology	Multiple tumor types	MMP inhibitor (Matrix Metalloprotease Inhibitor)	PPD	Mar-00		
Abt 560	Neuroscience	Attention deficit / hyperactivity disorder (ADHD), Alzheimer's Disease, cognition	e4b2 NNR (Nicotinic Neuronal Receptor)	GPRD	Dec-05	Pre clinical	



Glossary (cont.)

NME Compound	Therapeutic Area	Lead Indication(s)	Target / Compound Description	Source	DDC Date	Current Status	Other Information
Abt 567	Oncology	Multiple tumor types	TSP (Thrombospondin mimetic peptide that blocks tumor response to several growth factors)	GPRD	Feb-02	Terminated 2002	
Abt 627	Oncology	Prostate cancer	ETa (Endothelin Antagonist)	PPD	Dec-95	Phase III	
Abt 670	Urology	Erectile Dysfunction	D4 antagonist (D4 is a dopamine receptor)	GPRD	Oct-02	Terminated 2002	
Abt 724	Urology	Erectile Dysfunction	D4 antagonist (D4 is a dopamine receptor)	GPRD	Jul-01	Terminated 2002	
Abt 737	Oncology	Multiple tumor types	BCLx inhibitor (tumor growth inhibitor first identified in chicken B cell lymphoma)	GPRD	Dec-03	Terminated 2005	
Abt 751	Oncology	Multiple tumor types (Neuroblastoma)	Antimitotic - inhibits tumor cell replication	Elsai	Mar-00	Phase II	
Abt 769	Neuroscience	Epilepsy	VPA (Valproic Acid - Depakote follow on)	GPRD	Nov-02	Terminated 2002	
Abt 773	Anti-Infectives	Respiratory Infection	Kerolide - next generation macrolide (follow on for Biaxin)	PPD	Mar-97	Terminated 2002	
Abt 828	Oncology	Multiple tumor types	K5 (Kingle 5 portion of human plasminogen, inhibits blood supply formation of tumors)	PPD	Mar-00	Pre clinical	
Abt 834	Neuroscience	Attention deficit / hyperactivity disorder (ADHD), Alzheimer's Disease	H3 (Histamine 3 receptor agonist)	GPRD	Dec-02	Terminated 2004	
Abt 869	Oncology	Multiple tumor types	RTK (Tyrosine Kinase Inhibitor- inhibits blood supply formation of tumors)	GPRD	Jan-04	Pre clinical	
Abt 870	Renal	Iron Deficiency Anemia	Iron Oligosaccharide - novel delivery technology for iron	Pharmascience		Terminated 2005	
Abt 874	Immunology	Multiple Sclerosis, Psoriasis	anti-IL 12 (targets interleukin 12 pathway which is thought to be involved in MS and psoriasis)	Knoll/ABC		Phase II	
Abt 888	Oncology	Multiple tumor types (Melanoma)	PARP inhibitor (poly ADP-ribose polymerase inhibitor - enhances effectiveness of chemo and radiation therapy)	GPRD	Oct-05	Pre clinical	Backup for Abt 472

Glossary (cont.)

NME Compound	Therapeutic Area	Lead Indication(s)	Target / Compound Description	Source	DDO Date	Current Status	Other Information
AN 804	Neuroscience	Attention deficit / hyperactivity disorder (ADHD), Alzheimer's Disease, cognition	α1B2 NMR (Nociceptive Neuronal Receptor)	GPRD	Feb-03	Phase II	
	Pain	Neuropathic Pain (pain caused by neurologic disorders)					
AN 925	Neuroscience	Schizophrenia/Psychosis	D3 agonist (D3 is a dopamine receptor)	Kroil		Phase II	Re-initiated program in 2006
AN 953	Immunology	Pain (due to inflammation: osteo and rheumatoid arthritis)	Cox-2 inhibitor (NSAID (Non-steroidal anti-inflammatory) similar to Vioxx and Celebrex)	PPD	Jun-99	Terminated 2002	
HSR 903	Anti-infectives	Respiratory Infection	Quinolone class antibiotic	Kroil	Feb-94	Terminated 2003	
Huntra	Immunology	Rheumatoid arthritis	anti-TNF (Tumor Necrosis Factor)	Kroil/ABC		Launched 2002	
Nunax	Immunology	RSV (Respiratory Syncytial Virus)	Follow on for Synagis	Medimmune		Phase III	
Segard	Immunology	Septic shock	anti-TNF (Tumor Necrosis Factor)	Kroil		Terminated 2004	
Simdar (Larotimidin)	Acute Care	Acute Heart Failure	New class of compound for treating Acute Heart Failure	Orion		Phase III	



Glossary (cont.)

Term / Abbreviation	Definition	Detail
AS	Ankylosing Spondylitis	Arthritic condition of the spine
CD	Crohn's Disease	
CHD	Congenital Heart Disease	
Clar ER (EU)	Extended Release (European Union filing)	
DDC	Drug Development Candidate	Refers to discovery compound that has advanced to the point of selection for drug development.
DDI	Drug Drug Interaction	The characteristic of a drug to interact with another drug being taken by a patient.
Depakote ER Adult Mania	Extended Release (Adult Mania indication)	
Dilaudid OROS	OROS is a special extended release formulation developed by Alza	
Feno Acid	Parent drug of fenofibrate (Tricor)	
GLP Tox	Good Laboratory Practice Toxicity Studies	GLP toxicity studies are animal tox studies that are the official starting point of clinical development. Also referred to as "regulatory tox" studies.
GPRD MP Support	Refers to general GPRD R&D support of on-market projects	
HEOR	Health Economics and Outcomes Research	Studies targeted to demonstrate the economic value of drug therapies
IIS	Investigator initiated studies	Studies of Abbott on-market products by external investigators where Abbott is not the official sponsor nor controls the protocol of the studies
IND	Investigative New Drug Application	



Glossary (cont.)

Term / Abbreviation	Definition	Detail
JRA	Juvenile Rheumatoid Arthritis	
LCM	Life Cycle Management	
NME	New Molecular Entity	Refers to compounds in research or clinical development that have not yet been approved for use in humans. Includes biologics (NBE- New Biologic Entity) and small molecules (NCE- New Chemical Entity)
Omni AOM Double Dose	A double dose formulation of Omnicef targeted at Acute Otitis Media (middle ear infections)	
Omni OS	Omnicef Oral Suspension	
PS	Psoriasis	
PSA	Psoriatic Arthritis	
SIP1R	Sphingosine-1-phosphate-1 receptor	Clinical targets are MS and Crohn's Disease, mechanism of action is cell adhesion inhibitor.
Tricor FDC	Fixed Dose Combination of Tricor with a statin	
Tricor NFE	Formulation of Tricor that is not affected by amount of food when dosed	
UC	Ulcerative Colitis	Painful, debilitating intestinal disorder
Zemplar Capsule 3/4	3/4 refers to patients with Stage 3 and Stage 4 renal disease	
Zemplar Capsule 5	V refers to patients with Stage 5 renal disease	

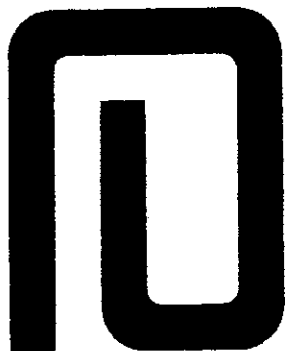


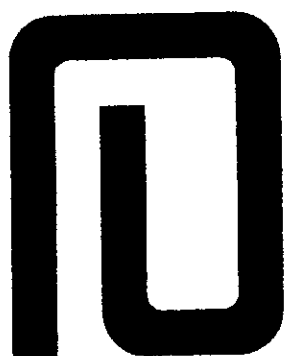
Agenda


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Appendix





GPRD 2006 Functional Expense Overview



The following pages Identify overall PPG R&D spend, and more specifically, GPRD spend by functional organization supporting Research and Clinical Development activities.

Overall, PPG Research and Development is driven by activities across GRPD, AI and PPD:

2006 Plan
Expense

Primary Activities

- Discovery efforts at Lake County, Worcester and Germany (LU)
- Clinical Development activities to achieve regulatory submissions
- Clinical Development supporting LCM and Marketed Products
- PPG Headquarter groups (HR, Regulatory Affairs, BD/Licensing)

GPRD

1,311

AI

115

Support of Country specific Marketed Product/LCM initiatives,
Medical, Regulatory and Legal requirements

PPD

6

Medical Liaisons - Develop and maintain relationships with opinion leaders

Total

1,432

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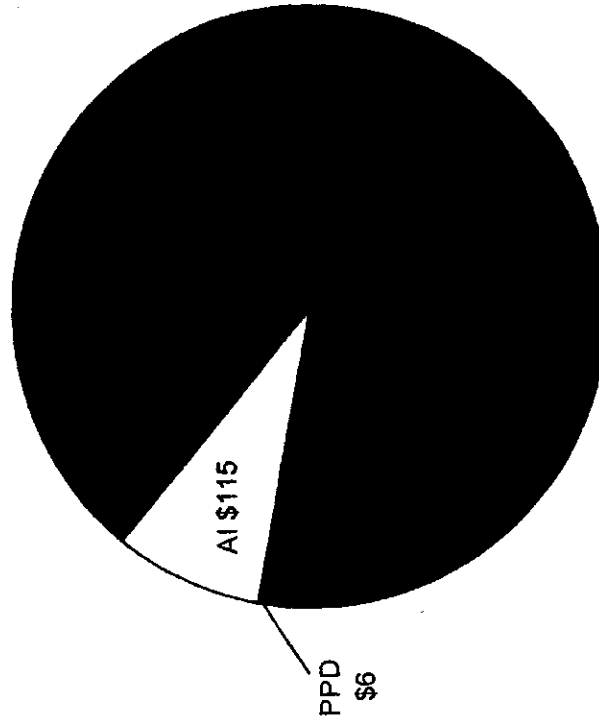
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2006 Plan - Total PPG R&D Expenditures (\$MM)

PPG R&D = \$1,432



\$MM

R&D:	
Gross Expense	1,352
Affordability	(22)
Non-R&D Project Support	(19) (a)
GPRD Controlled R&D	1,311
AI Controlled R&D	115
PPD Controlled R&D	6
Total PPG R&D	1,432

(a) Includes work performed for AVD, TAP, ADD, ROSS, and ANI.



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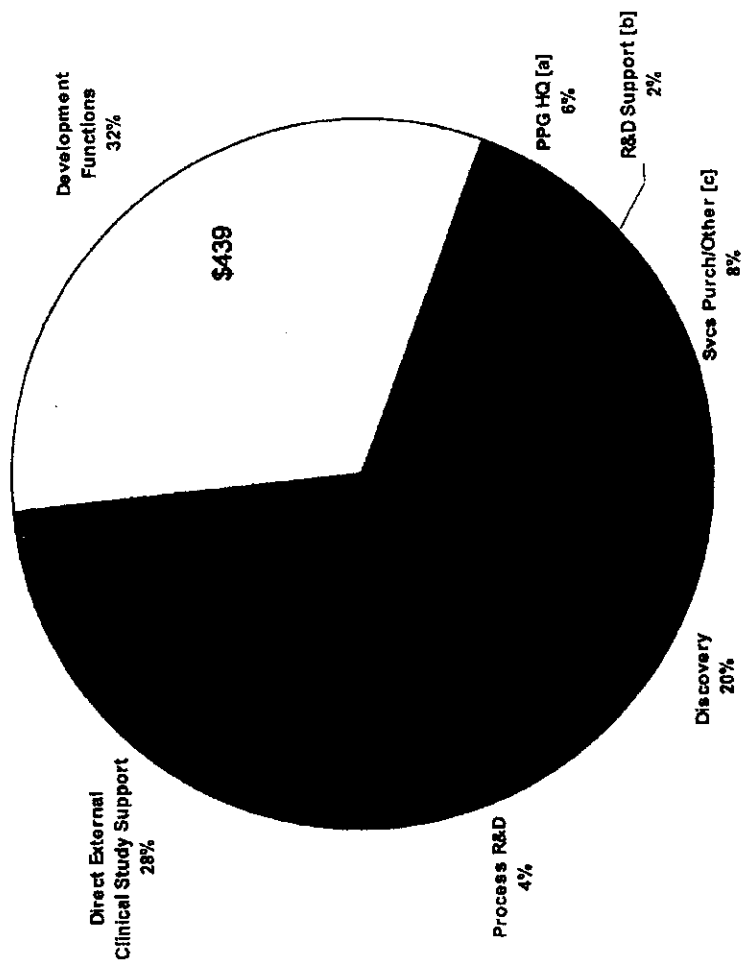
Global Pharmaceutical Research and Development 2006 Plan - Total GPRD Expenditures (\$MM)

GPRD Expense

Gross Expense
Affordability
Non-R&D Project Support
GPRD Controlled R&D

\$MM
\$1,352
(\$22)
(\$19)(d)
<u>\$1,311</u>

Total GPRD Gross Expense = \$1,352MM



- (a) PPG HQ - Regulatory Affairs, Scientific Affairs, and Licensing / New Business Development.
- (b) R&D Support - Laboratory Services, EH&S, HR, Finance.
- (c) Primarily Corporate allocations (Legal, Library, Cafeteria, Staffing, Corp. IT, Purchasing, Engineering, Etc.).
- (d) Includes work performed for AVD, TAP, ADD, ROSS and ANI.

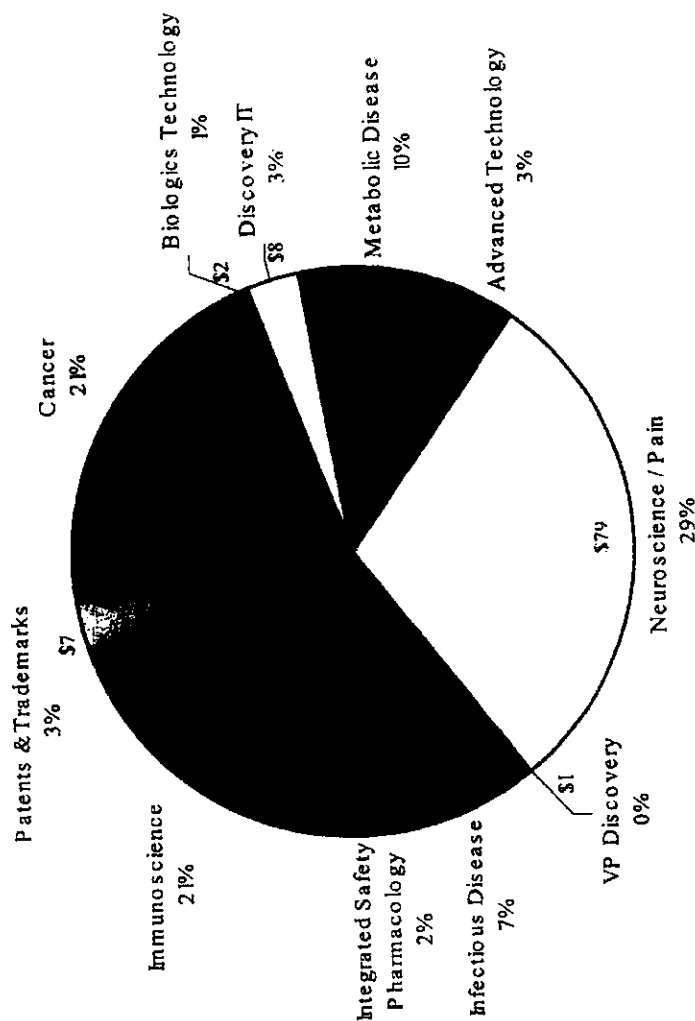


Global Pharmaceutical Research and Development 2006 Plan - Total Discovery Functional Expenditures

2006 Plan (Functional View)

Discovery	\$270	\$MM
Process R&D	\$51	
Dev. Internals	\$439	
Dev. Externals	<u>\$372</u>	\$811
PPG HQ Support	\$83	
Services Purchased/Other	\$104	
R&D Support	<u>\$33</u>	
Gross Expense	<u>\$1,352</u>	
Affordability	(\$22)	
Non-R&D Project Support	<u>(\$19)</u>	
GPRD Controlled R&D	<u>\$1,311</u>	

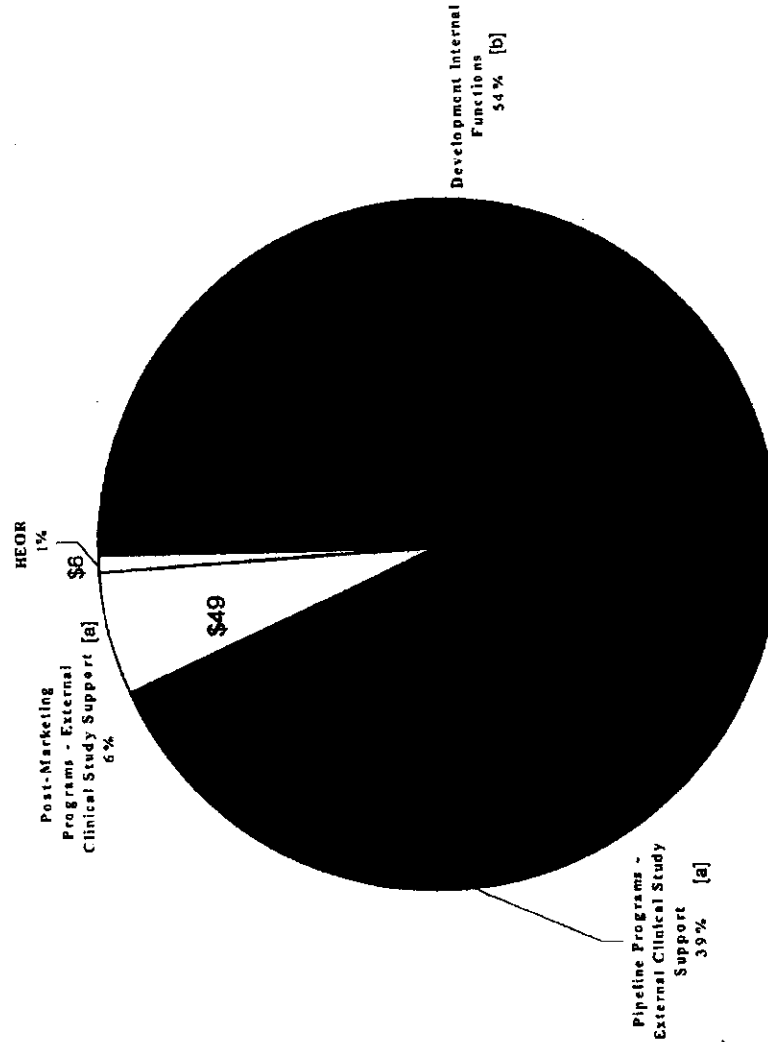
Total Discovery = \$270MM



Global Pharmaceutical Research and Development 2006 Plan - Total Development Expense

Total Development Expense = \$811MM

2006 Plan (Functional View)	\$MM
Discovery	\$270
Process R&D	\$51
Dev. Internals	\$439
Dev. Externals	<u>\$372</u>
	\$811
PPG HQ Support	\$83
Services Purchased/Other	\$104
R&D Support	<u>\$33</u>
Gross Expense	\$1,352
Affordability	<u>(\$22)</u>
Non-R&D Project Support	<u>(\$19)</u>
GPRD Controlled R&D	<u>\$1,311</u>



- (a) Direct "External" clinical study costs for CROs, Investigator Grants, Drug Supply, and Lab Analysis / Testing, etc.
- (b) "Internal" functions supporting development activities. Costs include Payroll, Employee Related, and Operating Expense.

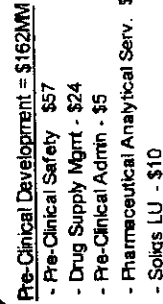


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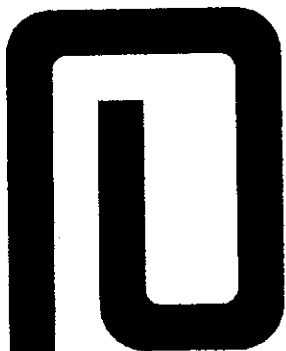
Total Internal Expense = \$439MM

Discovery	\$439	\$811	\$270	\$51	\$83
Process R&D					\$104
Dev Internals					\$39
Dev. External					\$1,352
					(\$22)
PPG HQ Support					(\$19)
Services Purchased/Other					\$1,311
R&D Support					
Grass Expense					
Affordability					
Non-R&D Project Support					
GRPD Controlled R&D					



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Other Info



Discovery spend, adjusted for organization transition impacts and exchange, has been held to a 1.9% CAGR in the 2002-2006 period while headcount is flat.

Global Discovery Spend	CAGR %		'02 - '06
	Reported	'02 - '05	
	Adjusted		
	Reported	6.6%	4.4%
	Adjusted	3.2%	1.9%

\$MM

382.5
375.2

Exchange

348.3

Organization
transition impacts

7.4

24.8

316.1

- Full-year impact of 2002 HC additions (ABC) 5
- BASF/ABT accounting policy harmonization (ABC) 4
- First-time purchase of GPO services in 2003 (ABC) 5
- Increased allocations to GPRD in 2003 (LC) 13
- First-time allocation of overhead in 2003 (Germany) 6
- Japan shutdown (elimination of 97 Discovery scientists) (8)

Organization transition impacts

25

2002
Reported

2002
Adjusted

2006
Plan

Year-End Headcount	1,365	1,305	1,355
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Global Discovery Headcount

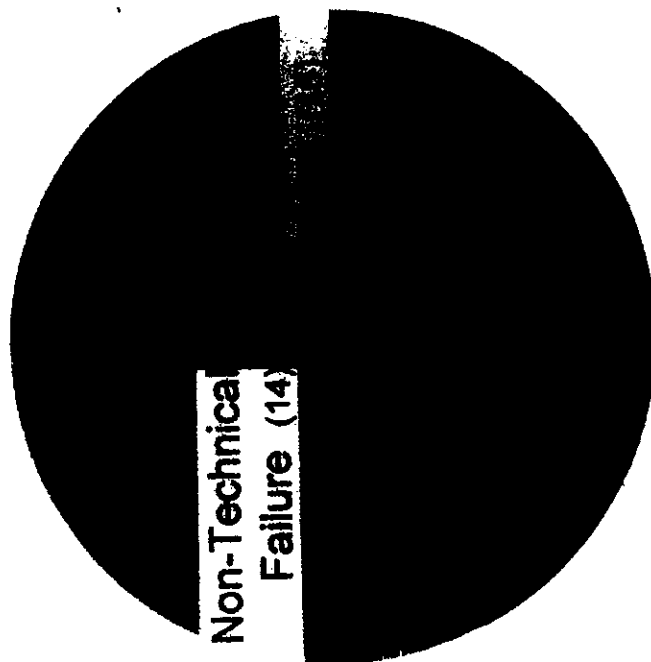
	1998	1999	2000	2001 (Acquisition)	Actuals			2006 Plan
					2002	2003	2004	
Therapeutic (LC)	652	662	688	686	765	763	742	758
Germany	-	-	-	240	121	130	131	132
ABC	-	-	-	167	209	234	234	240
Process R&D	35	56	54	319 (a)	240	213	192	195
Discovery IT	-	-	-	-	30	30	30	31
Japan	-	-	-	97	91	4	-	-

(a) Process R&D represents Chemical Science headcount prior to 2001. Beginning in 2001, Chemical Science headcount were combined with Process R&D (organization transition from CAPD/GPO in 2001).

(b) Excluding Japan, total headcount in 2002 equals 1,365.



1998 - present Approved DDC Status



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1998 - present Approved DDC Attrition – Technical Reasons

ABT Area	Target	DDC	Ended in	Reason
Safety/Toxicology				
259 Pain	NNR #2	Sep-98	Ph I	Low TI vs. nausea/vomiting AEs
598 Urology	KCO	Jul-00	GLP tox	class concern about cardio tox TI
239 Neuro	H3 #1	Nov-01	GLP tox	Replaced by 834 due to reduced QT and DDI concerns
202 Pain	NNR #3	Jun-02	Ph I	emesis and atrial fibrillation
769 Neuro	VPA	Nov-02	GLP tox	Teratology assessment conducted early to enable early kill
834 Neuro	H3#2	Dec-02	GLP tox	Testicular toxicity
Pharmacokinetics				
839 Oncology	FTI#1	Jul-98	Ph I	Half life too short even with Rit boosting
963 Immunology	Cox-2	Jun-99	Ph I	Very long half life
127 Neuro	D3 #1	Jun-03	Ph I	Not QD. Cyp induction -DDI
472 Oncology	PARP	Sep-03	GLP tox	Unique human plasma degradation. Still being pursued by Abbott animal health.
Safety and Pharmacokinetics				
770 Oncology	MMP#1	Sep-98	Ph I	Long lived metabolites and phospholipidosis
Safety and Efficacy				
100 Oncology	FTI #2	Jul-01	GLP-tox	Nerve degeneration seen in multidose toxicity. Competitors showed toxicity

12 DDCs



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1998 - present Approved DDC Attrition – Non-technical Reasons

ABT Area	Target	DDC	Ended in Reason
Patent			
866 Neuro	adrenergic	Oct-98	Patent issues arising post-DDC, prior to Tox
123 Oncology	RTK	Dec-02	Patent concerns developed post DDC. Pursuit of license dropped in favor of backup
Undeveloped Backup			
546 Oncology	ETa; B/U	Jul-98	Ph I Placed on hold to focus on Xinlay
797 Infectious	Macrolide	Mar-99	pre-GLP Follow-on to ABT-773 with better PK, available when it was uncertain if 773 could be QD.
567 Oncology	TSP#2	Feb-02	GLP Focus on ABT-510 first. Depot formulation developed. Held for life cycle management.
737 Oncology	Bcl 2 #1	Dec-03	pre-GLP Focus on ABT-263 (orally active backup)
362 Immunology	all-18 #2	Dec-04	pre-GLP On hold awaiting progression of ABT325, should be counted same as TSP #2
518 Oncology	MMP#2	Mar-00	Ph-I Low funding priority. Competitors with different selectivity and inferior PK failed in phase III
Divestiture			
724 Urology	D4 #1	Jul-01	Ph II Choose not to play in ED market. Offered for outlicensing
210 Infectious	Ketolide	Sep-02	pre-GLP De-emphasized antibacterials, offered for outlicensing
670 Urology	D4 #2	Oct-02	pre-GLP Choose not to play in ED market. Offered for outlicensing
441 Metabolic	GR antag	Dec-02	pre-GLP Being developed by Karabio
Revised Market Potential			
271 Oncology	taxane	Jul-98	pre-GLP Commercial potential judged less attractive following appearance of multiple taxanes.
677 Infectious	N'ram'ase	Nov-99	pre-GLP Market judged unattractive post Tamiflu launch



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